IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION This document relates to: *All Actions*	No. 1:19-md-2875-RBK Hon. Robert Kugler Hon. Joel Schneider

PLAINTIFFS' CONSOLIDATED MEMORANDUM OF LAW IN OPPOSITION TO MANUFACTURER, WHOLESALER, AND RETAIL PHARMACY DEFENDANTS' MOTIONS TO DISMISS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

OTHER AUTHORITIES

RULES

TREATISES

Co-Lead Plaintiffs' Counsel, on behalf of the Plaintiffs' Executive Committee, pursuant to the Court's May 18, 2020 Order (ECF 432), respectfully file this consolidated Memorandum of Law in Opposition ("Opposition") to the Motions to Dismiss filed by the Manufacturer, Wholesaler, and Retail Pharmacy Defendants (ECF 520-532).

INTRODUCTION

This multidistrict litigation ("MDL") involves one of the most expansive prescription pharmaceutical recalls in United States history, concerning three common generic blood pressure medications: valsartan, losartan, and irbesartan. These drugs were contaminated for years with unacceptable levels of carcinogenic nitrosamines as a result of Defendants' desire to put profits over patients. The consolidated claims in this MDL are for personal injuries, economic losses, and medical monitoring. Defendants' Motions to Dismiss and this omnibus Opposition relate solely to valsartan containing drugs ("VCDs"), not losartan or irbesartan containing drugs.

Valsartan is the generic version of the hypertension drug Diovan. In the 2000's, various generic drug manufacturers developed their own generic versions of Diovan (and a related combination product that included valsartan, called Exforge). Rather than use the same manufacturing process used by the brand manufacturer of Diovan and Exforge, each Manufacturer Defendant cut corners to increase their respective profits. The result of these manufacturing decisions led to the formation of N-nitrosodimethylamine ("NDMA") and other nitrosamines in the active pharmaceutical ingredient ("API") of the VCDs made by Manufacturer Defendants. NDMA and other nitrosamines are human carcinogens, and this was not an isolated or one-off impurity. The inherent, systemic flaws in the manufacturing processes resulted in the contamination of all or nearly all of Defendants' VCDs sold in the United States with an undisclosed, dangerous carcinogen.

Defendants at each stage of the distribution chain had independent obligations to ensure the products they sold were what they said they were – generic valsartan the "same" as the branded drug equivalents. These obligations also extended down the stream of commerce, requiring the Defendants who sell drugs to make certain they were sourcing VCDs from reputable generic manufacturers, who adhered to at least the minimum, base-line manufacturing and quality assurance practices. But no Defendant, be they Manufacturer, Wholesaler, or Retail Pharmacy, took adequate steps to detect or guard against the sale of contaminated VCDs to Plaintiffs, the foreseeable end-users and end-payors for the VCDs. What is more, the contamination certainly was known or knowable to each Defendant. Indeed, the FDA and similar regulatory bodies abroad acted swiftly when a third-party, believed to be Novartis (the manufacturer of Diovan), quickly discovered the contamination upon evaluating ZHP's active pharmaceutical ingredient ("API").

The nitrosamine contamination created an inherently dangerous pill, which, taken daily, caused hundreds or thousands of people to develop cancer. The nitrosamine contamination and associated rampant current good manufacturing practices ("cGMP") failures, among other things, also rendered Defendants' VCDs adulterated, misbranded, and economically worthless. Defendants had an obligation to ensure that the VCDs they sold were the "same" as Diovan and Exforge. But their VCDs were not the "same." Defendants' VCDs contained an off-label, non-FDA approved contaminant that is not present in Diovan or Exforge, let alone approved by the FDA for inclusion in any Defendant's VCD (or any other drug, for that matter).

Despite these well-pleaded allegations, Defendants challenge various factual predicates in their collective 120 pages of briefing. Their assertions range from what each Defendant might have known about the contamination (*e.g.*, Wholesaler Defendants' assertion that the contamination was "microscopic," so should be relieved of all liability, *see* Wholesaler Br. at 7; or Retail Pharmacy Defendants' proclamation that they "did not know and could not have known"

about the contamination, *see* Retail Pharmacy Br. at 28), to whether the contaminated VCDs "performed as expected" even if they poisoned consumers with undisclosed nitrosamines, *see* Mfr. Br. at 15. Such arguments might be pertinent at summary judgment but not here. Plaintiffs need not prove now what each Defendant knew (prior to fully developed merits discovery), or to spar with Defendants on the scope of damages sustained (prior to expert discovery). On a Rule 12(b) motion, the focus is on whether the allegations set forth a plausible basis for relief and whether Defendants are sufficiently on notice of those claims. The Master Complaints do just that.

Contrary to Defendants' assertions, the Master Complaints collectively lay out in 300+ pages of painstaking detail , allegations as to what each Defendant did, and when, how, and why they did it. The Master Complaints separately chronicle the history of manufacturing-related issues – documented in FDA inspection reports going back nearly a decade – at each Manufacturer Defendant's facilities that made VCDs or the valsartan API incorporated into the VCDs, and which all Defendants (Manufacturer, Wholesaler and Retail Pharmacy) sold. The Master Complaints adequately allege the adulteration of Defendants' VCDs and set forth the likely causes of the nitrosamine contamination. Plaintiffs are not alone in their conclusions – the FDA and similar regulatory bodies abroad concluded the same thing in their own investigations that led the FDA and other bodies to require the VCD recalls. The Master Complaints further describe how ordinary-course diligence at all distribution levels (such as the ordinary-course diligence that did uncover the nitrosamine contamination) should have detected the contamination, or at least suspected it. Simply put, the Master Complaints amply clear the "short and plain statement" hurdle.

Defendants' various merits-based legal arguments – *e.g.*, standing, preemption, claim-specific elements – fare no better. Each set of Plaintiffs here has standing to assert their claims. Personal Injury Plaintiffs developed cancer as a result of Defendants' conduct; Economic Loss and

Medical Monitoring Plaintiffs paid money for worthless, unapproved drugs; and Medical Monitoring Plaintiffs are entitled to ongoing screening for undisclosed, improper, and dangerous health risks created by Defendants. These are concrete, judicially remediable injuries traceable to Defendants' conduct. Article III standing requires nothing more.

Plaintiffs' claims are not preempted by federal law. Implied conflict or impossibility preemption does not apply. Defendants had identical obligations under federal and state law to ensure that their VCDs were the "same" as Diovan or Exforge. They failed to discharge those obligations. In these circumstances, holding Defendants liable for their failures under state law does not conflict with federal law, nor do Plaintiffs' theories of recovery render simultaneous compliance impossible. Further, there is nothing so specialized or unique here that might require this Court to abstain and refer this matter to the FDA.

The "subsumption" argument – the suggestion that certain states' product liability acts "subsume" or preclude all other state theories of liability – is not claim-determinative. It only addresses a small subset of the states' laws pled here, which alone is reason to deny dismissal of certain Counts in their entirety. Further, as but one example, just a few weeks ago, the Supreme Court of New Jersey explicitly held that its state product liability law does *not* subsume or preclude all other state law theories. The same is true in other states listed by Defendants.

Defendants' hodgepodge of "claim-specific deficiencies" does not attempt to carefully address the permutations of state law. Instead, Defendants submit 120-ish pages of charts – often completely untethered from argument – with laundry lists of cases and statutes used to make blanket and inaccurate assertions regarding the Master Complaints' state law claims.[1] Defendants

[1] Defendants' compendium of state law "authority" should be stricken. Not only is this a clear attempt to circumvent Defendants' own self-imposed (and generous) 120-page limitation by attaching another 112 pages of legal argument, but each chart purposefully glosses over the factual

have fired no silver bullet. At best, Defendants only address a subset of states' laws under each Count of the Master Complaints, implicitly conceding that the overall claims or theories remain viable under many other states' laws. Thus, dismissal of any Count in its entirety is improper. Further, piecemeal dismissal of Counts on a state-by-state basis is inappropriate and inefficient at this early stage. Last, and most importantly, Defendants' charts misstate the laws they purport to summarize.

Finally, the Court should reject Wholesaler and Retail Pharmacy Defendants' attempts to cast themselves as mere pass-throughs or blameless victims entirely immune from liability. Retailer Pharmacy Defendants sold the contaminated VCDs to Plaintiffs and other consumers. They had their own obligations to the consumers to ensure that the products they sold were merchantable, non-misleading, and of represented quality. They fell short of this in selling adulterated, misbranded, and worthless VCDs to Plaintiffs, with whom they were in direct privity. Similarly, Wholesaler Defendants had their own obligations in selling and profiting on contaminated VCDs. A wholesaler cannot profit on the sale of a misbranded, adulterated, and dangerous product they put into the stream of commerce.

In sum, this is not a haphazard case based on some slapdash theory couched in vague conjecture. The allegations are specific, detailed, plausible, rooted in regulatory reports (some of which were unavailable or redacted prior to core discovery in this case), and, above all, legally sufficient. The harm to Plaintiffs was particularized and real. The allegations here satisfy the pleadings standard at this early pre-discovery stage. For the foregoing reasons, as discussed more fully below, the Court should deny Defendants' motions to dismiss.

---

inquiries necessary to determine whether the elements of those claims or defenses have been met, or whether certain exceptions are met based on a full developed factual inquiry. Plaintiffs highlight the fallacy of these charts by attaching their own rebuttal charts for certain state law claims, or otherwise addressing them in this brief.

I. BACKGROUND

The Personal Injury Master Complaint ("PIMC") (ECF 122), Economic Loss Master Complaint ("ELMC") (ECF 398) and Medical Monitoring Master Complaint ("MMMC") (ECF 123) contain nearly identical factual allegations, which are briefly set forth *infra* Part I.A.

The ELMC alleges an "economic damages action" based on Defendants' sale of VCDs that were "of a lesser quality and were adulterated and/or misbranded (and thereby rendered worthless) through contamination with" nitrosamines and on account of rampant and serious failures to adhere to FDA regulations regarding current Good Manufacturing Practices ("cGMPs") and state laws paralleling same. ELMC ¶ 4. The ELMC brings eighteen claims on behalf of classes of consumers and third-party payors ("TPPs") in order to recoup the amounts that they paid for Defendants' worthless VCDs. ELMC ¶ 10, Prayer for Relief ¶ E.

The claims in the MMMC are based on Defendants' nitrosamine-contaminated VCDs and related misrepresentations and/or omissions causing the Class Plaintiffs' "cellular damage, genetic harm, and/or . . . an increased risk of developing cancer." MMMC ¶ 1. It has nine claims seeking "injunctive and monetary relief, including creation of a fund to finance independent medical monitoring services, … notification to all people exposed to this contamination, examinations, testing, preventative screening, and care and treatment of cancer resulting, at least in part, from the exposure to the NDMA or NDEA contamination." *Id.*

The PIMC stems from "Plaintiffs' development of cancers, as a result of taking an adulterated, misbranded, and unapproved medication designed, manufactured, marketed, distributed, packaged, and sold by Defendants." PIMC ¶ 2. It contains fourteen claims for personal injury and economic losses related to the cancer caused by Defendants' nitrosamine-contaminated VCDs.

Each Master Complaint adequately pleads its claims. However, to the extent discussed in each of the following sections, leave to amend the Master Complaints should be granted as necessary. A district court should grant leave to amend a complaint unless "'(1) the moving party has demonstrated undue delay, bad faith or dilatory motives, (2) the amendment would be futile, or (3) the amendment would prejudice the other party.'" *United States ex rel. Customs Fraud Investigations, LLC v. Victaulic Co.*, 839 F.3d 242, 249 (3d Cir. 2016) (quoting *United States ex rel. Schumann v. Astrazeneca Pharm. L.P.*, 769 F.3d 837, 849 (3d Cir. 2014)). Given this liberal rule, the Third Circuit has "rarely upheld a dismissal with prejudice of a complaint when the plaintiff has been given no opportunity to amend." *Id.* at 250. As discussed in each section below, Plaintiffs do not request leave to amend in order to delay this case or for any other dilatory reason, and the amendments will not be futile or prejudice Defendants. The Court should consequently grant Plaintiffs' leave to amend the Master Complaints as necessary.

A. Facts Pleaded

1. Valsartan

Valsartan and its combination therapy with hydrochlorothiazide are the generic versions of the registered listed drugs ("RLDs") Diovan® ("Diovan") and Diovan HCT® ("Diovan HCT"), respectively. *See* PIMC ¶ 9; ELMC ¶ 3; MMMC ¶ 2. Amlodipine-valsartan and its combination therapy with hydrochlorothiazide are the generic versions of the RLDs of Exforge® ("Exforge") and Exforge HCT® ("Exforge HCT"), respectively. These RLDs are indicated for, *inter alia*, the treatment of high blood pressure, a condition affecting approximately 103 million Americans according to the American Heart Association. Several million U.S. patients pay for (in whole or in part) and consume generic valsartan each year. *See* PIMC ¶ 9; ELMC ¶3; MMMC ¶ 2.

The United States Food and Drug Administration ("FDA") approved Diovan and Diovan HCT respectively in March 1998 and July 2001. Since then, these branded drugs have

been continuously manufactured, marketed, and sold under those trade names by Novartis A.G. ("Novartis"), a Swiss brand pharmaceutical company. Novartis's Exforge and Exforge HCT were approved by the FDA in June 2007 and April 2009, respectively.

Diovan and Exforge proved to be blockbuster drugs for Novartis. These drugs' huge commercial success attracted attention from various generic drug manufacturers. However, Novartis enjoyed patent protection on its original Diovan patents through 2012, which blocked entry of generic competition until then. Novartis's patent protection, however, did not stop ZHP and other Defendants from preparing to launch their own generic valsartan almost a decade prior to patent expiry. *See* PIMC ¶ 242; ELMC ¶ 211; MMMC ¶ 173.

2. Overview of the Generic Drug Approval Process in the United States

All branded drugs sold in the United States first require FDA approval. To obtain this approval, a brand drug company must submit a New Drug Application ("NDA") to the FDA that demonstrates clinical safety and efficacy through well-designed clinical trials. 21 U.S.C. 355, *et seq*. By contrast, generic drug companies submit an Abbreviated New Drug Application ("ANDA"). Instead of demonstrating clinical safety and efficacy through clinical trials, ANDA applicants need to demonstrate that their proposed drug is the generic equivalent to the brand or reference listed drug ("RLD"). Bioequivalence is the "absence of significant difference" in the pharmacokinetic profiles of two pharmaceutical products. 21 C.F.R. § 320.1(e).

Generic drug manufacturers have an ongoing federal duty of sameness in their products. Under 21 U.S.C. § 355(j), the generic manufacturer must show that the drug is the generic equivalent or copy of the RLD, including for example that the active pharmaceutical ingredient ("API") is the same as the RLD, § 355(j)(2)(A)(ii); and, that the generic drug is "bioequivalent" to the RLD and "can be expected to have the same therapeutic effect," *id.* at (A)(iv). The API is the part of any drug that produces the intended effects.

The excipient is any substance other than the API that helps deliver the medication to the human body system. While in certain specific instances generic manufacturers may use different excipients in the formulation of their generic drugs (provided they do not affect bioequivalence), the API must be the same. A generic manufacturer (like a brand manufacturer) must also make "a full statement of the composition of such drug" to the FDA. *Id.* at (A)(vi); *see also* § 355(b)(1)(C). In other words, a generic drug manufacturer must ensure that its generic product is the generic equivalent of the branded drug.

Prior to submitting an ANDA, a generic drug manufacturer may submit a Drug Master File ("DMF") to the FDA. DMFs are submissions to the FDA used to provide confidential, detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of the API which make up all prescription drugs. Unlike ANDAs, DMFs are neither approved nor disapproved. Rather, the FDA simply reviews the technical contents of the DMF when the agency ultimately receives, reviews, and decides on whether to approve an ANDA.

3. Carcinogenicity of Nitrosamines

Nitrosamines are known human carcinogens. Their only commercial purpose is to induce cancer in laboratory mice. N-nitrosodimethylamine, commonly known as NDMA, is an odorless, yellow liquid. *See* PIMC ¶ 145; ELMC ¶ 303; MMMC ¶ 266. According to the U.S. Environmental Protection Agency, "NDMA is a semivolatile chemical that forms in both industrial and natural processes." *See* PIMC ¶ 146; ELMC ¶ 304; MMMC ¶ 267. Exposure to high levels of NDMA has been linked to internal organ damage and cancer in humans. *See, e.g.*, PIMC ¶¶ 151, 153; ELMC ¶¶ 309, 311; MMMC ¶¶ 272, 274. Other nitrosamines, with similarly carcinogenic properties, include N-Nitrosodiethylamine ("NDEA") and N-Nitroso-N-methyl-4-aminobutyric acid ("NMBA"). *See, e.g.*, PIMC ¶¶ 157-158, 165; ELMC ¶¶ 317-318, 345; MMMC

¶¶ 280-281, 312. No nitrosamine is identified as an active or inactive ingredient, component, or intended or accepted impurity in the NDA for Diovan or Exforge, the branded valsartan products. *See* PIMC ¶¶407, 417, 484; ELMC ¶¶ 407, 161, 209; MMMC ¶¶ 123, 171, 383

4. The Defendants in This Litigation

The following briefly summarizes the Valsartan Defendants in this matter.

a. Manufacturer Defendants

Defendant ZHP is a Chinese company that manufactures pharmaceutical drugs and sells them worldwide. It owns or operates a number of affiliated entities in China and abroad to facilitate its development, manufacture, and sale of generic drugs. Through its wholly-owned and operated subsidiaries, ZHP controls every aspect of generic drug development, manufacture, and sale of its pharmaceutical products. ZHP manufactured both the valsartan API as well as finished dose VCDs during the relevant period. In the United States, ZHP directed the activities of multiple entities, including Defendants Huahai U.S. ("Huahai"), Prinston Pharmaceuticals ("Prinston"), and Solco Healthcare US, LLC ("Solco"), to market and distribute ZHP's VCDs. *See* PIMC ¶¶ 20-60, 200, 356-361; ELMC ¶¶ 49-55, 343, 367-372; MMMC ¶¶ 21-27; 310, 333-338.

Defendants Mylan Laboratories, Ltd., Mylan N.V., and Mylan Pharmaceuticals, Inc., (collectively, "Mylan") comprise a vertically integrated global API and drug manufacturer. During the relevant time period, Mylan manufactured valsartan API and finished dose VCDs. *See* PIMC ¶¶ 69-73; ELMC ¶¶ 62-67; MMMC ¶¶ 34-39.

Defendants Aurobindo Pharma, Ltd. and Aurobindo Pharma USA, Inc., (collectively, "Aurobindo") comprise a vertically integrated global API and drug manufacturer. During the relevant time period, Aurobindo manufactured valsartan API and finished dose VCDs. *See* PIMC ¶¶ 80-84; ELMC ¶¶ 68-72; MMMC ¶¶ 40-44.

Defendants Hetero Labs, Ltd., Hetero Drugs, Limited, Hetero USA Inc., and Camber Pharmaceuticals, Inc. (collectively, "Hetero"), comprise a vertically integrated global API and drug manufacturer. During the relevant time period, Hetero manufactured valsartan API and finished dose VCDs. *See* PIMC ¶¶61-64; ELMC ¶¶ 56-61; MMMC ¶¶ 28-33.

Defendants Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA, Inc., Arrow Pharma Malta Ltd., Actavis Pharma, Inc., Actavis, LLC (collectively, "Teva") manufactured and sold finished dose VCDs during the relevant time period. Teva purchased valsartan API from ZHP and Mylan. *See* PIMC ¶¶ 41-42, 74-75, 78-89; ELMC ¶¶ 73-77; MMMC ¶¶ 45-50.

Defendants Torrent Private Limited, Torrent Pharmaceuticals, Ltd., Torrent Pharma, Inc. (collectively "Torrent") manufactured and sold finished dose VCDs during the relevant time period. Torrent purchased valsartan API from ZHP. *See* PIMC ¶¶ 45-48; ELMC ¶¶ 78-81; MMMC ¶¶ 51-54.

b. Wholesaler Defendants

Wholesalers purchased bulk VCDs from one or more of the Manufacturer Defendants during the relevant time period, and in turn resold them to retail pharmacies to be dispensed to consumers. The three Wholesaler Defendants here, AmerisourceBergen ("AmerisourceBergen"), Cardinal Health, Inc. ("Cardinal"), and McKesson Corporation ("McKesson"), comprised over 90% of the wholesale drug market during the relevant time period. *See, e.g.*, ELMC ¶¶ 109 n.13; MMMC ¶ 89 n.12.

c. Repackager / Relabeler Defendants

Repackager and relabelers are entities that obtain drugs in bulk from manufacturers or wholesalers, and then repackage or relabel the drugs into smaller quantities for sale to pharmacies, doctor's offices, and others. At present, all Repackager/Relabeler Defendants save one (which has

not moved to dismiss) have availed themselves of the court-approved process for the dismissal without prejudice of certain defendants.

d. Retail Pharmacy Defendants

Retail pharmacies have supply arrangements with finished dose manufacturers or wholesalers to obtain prescription drugs to dispense to consumers. Retail pharmacies stand in direct contractual privity with consumers, insofar as retail pharmacies (both brick-and-mortar and mail-order) are entities that dispensed drugs and received payments for VCDs from consumers and TPPs. The Retail Pharmacy Defendants here are Walgreens Boots Alliance, Inc. ("Walgreens"), CVS Health Corp. ("CVS"), Walmart Stores, Inc. ("Walmart"), Rite-Aid Corp. ("Rite-Aid"), Express Scripts, Inc. ("Express Scripts"), The Kroger Co. ("Kroger"), OptumRx, Alberston's LLC ("Alberston's"), and Humana Pharmacy, Inc. ("Humana Pharmacy"). *See* PIMC ¶¶ 85-124; ELMC ¶¶ 82-108; MMMC ¶¶ 55-88.

5. Defendants' Development and Sale of Contaminated Valsartan API and VCDs

Each Manufacturer Defendant undertook to develop and commercialize its own valsartan API and/or finished dose VCDs by submitting their own ANDAs or DMFs. Each Manufacturer Defendant had an ongoing federal duty of "sameness" under the FDCA and FDA regulations – that is, to ensure their VCDs have the same composition and labeling as branded Diovan or Exforge. *See, e.g.*, PIMC ¶¶ 223-26; ELMC ¶¶ 201-204; MMMC ¶¶ 155-57.

Each Manufacturer Defendant, however, had inadequate processes that resulted in adulterated, misbranded, or unapproved VCDs.

Manufacturer Defendants (both in terms of those who manufactured API, and those who manufactured finished dose) were engaging in widespread grossly inadequate manufacturing practices dating back from before the drugs even entered the United States market. Defendants' non-compliance with cGMPs is likely part of the reason the contamination occurred in the first

place and was not recognized or resolved early on (even though, e.g., peaks in testing data should have alerted them to this). *See, e.g.*, PIMC ¶¶ 266-345; ELMC ¶¶ 233-311; MMMC ¶¶ 186-265.

Investigations into the facilities operated by the four API manufacturers here – ZHP, Mylan, Aurobindo and Hetero – show grossly inadequate quality control measures in place. FDA investigations found the following:

- Few or no codified processes or procedures for dealing with testing and sampling of product to ensure it met specifications (*see, e.g.*, PIMC ¶¶ 272, 290, 293; ELMC ¶¶ 239, 256, 259; MMMC ¶¶ 192, 254, 257);

- Inadequate and unsanitary facilities, including use of loose buckets to collect condensation and storage facilities infested with insects (*see, e.g.*, PIMC ¶¶ 294, 299, 311); ELMC ¶¶ 260, 265, 277; MMMC ¶¶ 229, 264, 258);

- Evidence that data was being intentionally and/or recklessly destroyed to avoid creating records of failed testing and sampling (*see, e.g.*, PIMC ¶¶ 198, 324, 334; ELMC ¶¶ 290, 300, 348; MMMC ¶¶ 207, 242, 308);

- Lack of adequate backup measures in place to ensure a data backup in the event of a largescale electrical error or outage (*see, e.g.*, PIMC ¶ 298; ELMC ¶ 264; MMMC ¶ 263);

- Data of testing kept in loose handwritten notebooks (*see, e.g.*, PIMC ¶ 296; ELMC ¶ 262; MMMC ¶ 261); and

- Evidence that employees were shredding documents prior to FDA investigations (*see, e.g.*, PIMC ¶¶ 324, 334; ELMC ¶¶ 290, 300; MMMC ¶¶ 207, 242).

To illustrate the above in more detail, ZHP, as both a valsartan API and finished-dose manufacturer, originally developed a four-step process for the manufacture of valsartan API. *See* ECF 296 at 3-4; *see also* PIMC ¶¶ 167, 280; ELMC ¶¶ 246, 336; MMMC ¶¶ 199, 289. To facilitate the chemical reaction necessary to form the specific tetrazole ring structure in these sartans, Process I utilized multiple chemical agents including tributyl tin chloride. *See* ECF 296 at 3-4. This agent was the same one used by Novartis to manufacture the valsartan API in its branded Diovan and Exforge products, as publicly disclosed in Novartis's NDA on file with

the FDA. However, this process was disfavored by ZHP for a host of reasons, the chief of which was cost. *See* ECF 296 at 4-5; *see also* PIMC ¶ 280; ELMC ¶ 246; MMMC ¶¶ 199.

ZHP could not yet sell its generic valsartan in the United States because of Novartis's patent protection until at least 2012, but ZHP could and did begin selling generic valsartan in other countries. *See* ECF 296 at 4-7; *see also* PIMC ¶ 143; ELMC ¶ 219; MMMC ¶ 179. ZHP's first manufacturing process was expensive. To cut costs, ZHP devised a second process – Process II – which substituted a different, cheaper chemical agent – triethylamine hydrochloride ("TEA") – in step 4 in lieu of tributyl tin chloride. *See* ECF 296 at 5; *see also* PIMC ¶ 280; ELMC ¶ 246; MMMC ¶ 199. Process II also replaced the solvent used in Process I (xylene) with a different solvent (toluene). Toluene is a cheaper, yet more volatile solvent agent. Nevertheless, replacing Process I with Process II yielded ZHP's intended result – the substitution of cheaper chemical agents reduced ZHP's costs and increased its profits for overseas valsartan sales. *See* ECF 296 at 5; *see also* PIMC ¶ 280; ELMC ¶ 246; MMMC ¶ 199.

Setting the stage for its profits-driven process-switch abroad, in January 2010 ZHP (through its United States subsidiaries), filed a second DMF with the FDA. This new DMF listed the same process change – Process I to Process II – that ZHP implemented for its non-United States valsartan. *See* ECF 296 at 29; *see also* PIMC ¶ 280; ELMC ¶ 246; MMMC ¶ 199. In its submission, ZHP explicitly acknowledged that switching from tributyl tin chloride to cheaper triethylmaine hydrochloride reduced the "economic cost" to make valsartan API. *Id.* What ZHP did not admit was that its decision to cut costs to pursue greater profits resulted in carcinogenic contamination of its valsartan API made pursuant to Process II.

As the FDA later found, ZHP's process change resulted in the creation of nitrosamines. *See, e.g.*, PIMC ¶ 280; ELMC ¶ 246; MMMC ¶ 199. The reason Defendants' manufacturing process produced these compounds is linked to the tetrazole ring that most ARB drugs have,

including VCDs. Solvents used to produce the tetrazole ring, such as N-Dimethylformamide (DMF), can result in the formation of drug impurities or new active ingredients, such as NDMA and NDEA, as a byproduct of the chemical reactions. The pharmaceutical industry has been aware of the potential for the formation of nitrosamines in pharmaceutical drugs at least as far back as 2005, if not earlier. According to the European Medicines Agency ("EMA") – which has similar jurisdiction to that of the FDA – "NDMA was an unexpected impurity believed to have formed as a side product after [ZHP] introduced changes to its manufacturing process in 2012." *Id.*

ZHP's long history of deviations from the FDA's cGMP standards led to the circumstances where nitrosamine contamination was likely in the first place. *See* PIMC ¶¶ 268-85, 177; ELMC ¶¶ 235-51; MMMC ¶¶ 188-204. From at least March 2007 forward, inspection after FDA inspection revealed troubling "deviations from current good manufacturing processes" at ZHP's manufacturing facility where it ultimately made valsartan API. *See* PIMC ¶ 271; ELMC ¶ 238; MMMC ¶ 191. For instance, the FDA's inspection of ZHP's same Xunqiao facility on November 14-18, 2016 revealed four violations of cGMPs. First, the FDA found that "[w]ritten procedures designed to prevent contamination of drug products purporting to be sterile are not followed." *See* PIMC ¶ 272; ELMC ¶ 239; MMMC ¶¶ 192. Second, ZHP had failed "to establish laboratory controls that include scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality, and purity." *See* PIMC ¶ 272; ELMC ¶ 239; MMMC ¶¶ 192. Third, the FDA noted that "[p]rocessing areas are deficient regarding the system for cleaning and disinfecting the equipment." Last, and most egregiously, the FDA observed that "data is not recorded contemporaneously." *See* PIMC ¶ 272; ELMC ¶ 239; MMMC ¶ 192.

On May 15-19, 2017, the FDA inspected ZHP's facility at Coastal Industrial Zone, Chuannan No. 1 Branch, Linhai City, Zhejiang Province, China. ZHP manufactures all of its

valsartan API at this Chuannan facility. *See* PIMC ¶ 273; ELMC ¶ 240; MMMC ¶ 193. That inspection resulted in the FDA's finding that ZHP repeatedly re-tested out of specification ("OOS") samples until obtaining a desirable result. This practice allegedly dated back to at least September 2016. The May 2017 inspection also resulted in FDA's finding that "impurities occurring during analytical testing are not consistently documented/quantitated." These findings were not made fully available to the public. However, this information was shared or available to ZHP's finished-dose manufacturers, as well as those Defendants further down the distribution chain. *See* PIMC ¶ 273; ELMC ¶ 240; MMMC ¶ 193.

Furthermore, for OOS sampling results, ZHP routinely invalidated these results without conducting any kind of scientific investigation into the reasons behind the OOS sample result. In one documented instance, the OOS result was attributed to "pollution from the environment" surrounding the facility. These manipulations of sampling were components of a pattern and practice of systematic data manipulation designed not to detect and/or intentionally conceal and recklessly disregard the presence of harmful impurities such as NDMA and NDEA. *See, e.g.*, PIMC ¶ 275; ELMC ¶ 241; MMMC ¶ 194.

The May 2017 inspection also found that ZHP's "facilities and equipment [were] not maintained to ensure [the] quality of drug product" manufactured at the facility. These issues included the FDA's finding that: equipment that was rusting and rust was being deposited into drug product; equipment was shedding cracking paint into drug product; there was an accumulation of white particulate matter; and there were black metallic particles in API batches. The FDA inspector "noted reoccurring complaints pertained to particulate matter in API . . . and for discrepancies in testing between [ZHP] and their consignees. . . . . To address the firm's handling of complaints describing testing disparities, [the inspector] had the firm generate a list of such complaints, as well as associated pie charts . . . . From 2015 until May 2017, 13 complaints

related to discrepancies between [ZHP]'s test results and their consignees' [own test] results." *See* PIMC ¶¶ 276-277; ELMC ¶¶ 242-243; MMMC ¶¶ 195-196.

On November 29, 2018, the FDA issued Warning Letter 320-19-04 to ZHP based on its July 23 to August 3, 2018 inspection of ZHP's Chuannan facility. The letter summarized "significant deviations from [cGMPs] for [APIs]." The FDA consequently informed ZHP that its "API are adulterated and/or misbranded within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B)." The FDA explained that ZHP repeatedly failed "to ensure that quality-related complaints are investigated and resolved," including complaints related to peaks of NDMA in its products as early as 2012. *See* PIMC ¶¶ 278-279; ELMC ¶¶ 244-245; MMMC ¶¶ 197-198.

ZHP also failed "to evaluate the potential effect that changes in the manufacturing process may have on the quality of [its] API." *See* PIMC ¶ 280; ELMC ¶ 246; MMMC ¶ 199. More specifically, ZHP "approved a [V]alsartan API process change . . . that included the use of the solvent [redacted]. [ZHP's] intention was to improve the manufacturing process, increase product yield, and lower production costs. However, [ZHP] failed to adequately assess the potential formation of mutagenic impurities, [such as NDMA,] when [it] implemented the new process. Specifically, [it] did not consider the potential for mutagenic or other toxic impurities to form from [redacted] degradants, including the primary [redacted] degradant, [redacted]. According to [ZHP's] ongoing investigation, [redacted] is required for the probable human carcinogen NDMA to form during the valsartan API manufacturing process." *See* PIMC ¶ 280; ELMC ¶ 246; MMMC ¶ 199. The FDA added that ZHP "also failed to evaluate the need for additional analytical methods to ensure that unanticipated impurities were appropriately detected and controlled in [its] [V]alsartan API before [it] approved the process change. [ZHP is] responsible for developing and

using suitable methods to detect impurities when developing, and making changes to, [its] manufacturing processes." *See* PIMC ¶ 281; ELMC ¶ 247; MMMC ¶ 200.

While ZHP claimed that it had followed "common industry practice, the FDA reminded ZHP that "common industry practice may not always be consistent with CGMP requirements and that [it is] responsible for the quality of drugs [it] produce[s]." *See* PIMC ¶ 282; ELMC ¶ 248; MMMC ¶ 201.

On September 28, 2018, the FDA prohibited ZHP from shipping drugs made at its Chuannan facility to the United States. *See* PIMC ¶ 283; ELMC ¶ 249; MMMC ¶ 202. After the recalls of ZHP's VCDs, FDA Laboratory Analysis testing would later reveal that valsartan API manufactured by ZHP at its Linhai City facilities contained NDMA levels hundreds of times in excess of the FDA's interim limits of 96 ng/day or 0.3 ppm. *See* PIMC ¶¶ 284-285; ELMC ¶¶ 250-251; MMMC ¶ 203. Specifically, VCDs manufactured at ZHP for ZHP's subsidiary Prinston Pharmaceutical contained NDMA levels of between 15,180 and 16,300 ng. To be clear, ZHP's VCDs should not have contained any NDMA. In addition, FDA Laboratory Analysis testing would later reveal that valsartan API manufactured by ZHP at ZHP's Linhai City facilities for Torrent Pharmaceuticals contained NDEA levels upwards of fifty times in excess of the FDA's interim limits of 26.5 ng/day or 083 ppm. *See* PIMC ¶ 285; ELMC ¶ 251; MMMC ¶ 204. Specifically, FDA testing reveals up to 1,310 ng of NDEA in Torrent Pharmaceuticals' VCDs. ZHP's valsartan API manufactured for Teva contained similarly high levels of NDEA (up to 770 ng). *See* PIMC ¶ 285; ELMC ¶ 251; MMMC ¶ 204.

The pattern above for ZHP – faulty manufacturing processes, exacerbated by rampant cGMP violations, which the FDA ultimately cited in part for requiring a VCD recall – is essentially the same for each of the other Manufacturer Defendants that made valsartan API: Mylan (*see* PIMC ¶¶ 301-333; ELMC ¶¶ 267-297; MMMC ¶¶ 219-249), Aurobindo (*see* PIMC ¶¶ 286-300;

ELMC ¶¶ 252-266; MMMC ¶¶ 250-265), and Hetero (*see* PIMC ¶¶ 332-345; ELMC ¶¶ 298-311; MMMC ¶¶ 205-218). The same is also true for the finished dose only Manufacturer Defendants: Teva (*see* PIMC ¶¶ 204-205; ELMC ¶¶ 250-251; MMMC ¶¶ 203-204), and Torrent (*see* PIMC ¶¶ 284-285; ELMC ¶¶ 250-251; MMMC ¶¶ 203-204).

6. Defendants Knew or Should Have Known About the Nitrosamine in Their Valsartan API and VCDs

Each Defendant had actual or constructive notice of nitrosamine contamination in their VCDs, yet did nothing to sequester the contaminated product or to ensure the VCDs they did sell were not contaminated. *See, e.g.*, PIMC ¶¶ 186-212; ELMC ¶¶ 338-353; MMMC ¶¶ 296-311. NDMA, NDEA, and any other nitrosamine are not FDA-approved ingredients for Diovan, Exforge, or their generic equivalents. The potential for nitrosamine creation during the chemical synthesis of the API in a drug is well-established and long-known. *See* PIMC ¶¶ 166-168; ELMC ¶¶ 337; MMMC ¶¶ 290. The scientific literature reported that the chemical reactions to form desired chemical compounds could lead to the unwanted creation of nitrosamines as well. Moreover, none of Defendants' VCDs identify NDMA, NDEA, or other nitrosamines as an ingredient on the products' labels or elsewhere. This is because these nitrosamines are probable human carcinogen active ingredients and are not approved to be included in valsartan API. Their inclusion in Defendants' VCDs renders the VCDs adulterated and misbranded compared to Defendants' warranties and representations. *See* PIMC ¶¶ 186-187; 346-355; ELMC ¶¶ 360-375; MMMC ¶¶ 318-332.

B. Plaintiffs' Detailed Allegations Are Not "Shotgun Pleadings"

Defendants' suggestions that Plaintiffs' Complaints are impermissible "shotgun pleadings," are simply wrong. *See* Mfr. Br. at 1; Wholesaler Br. at 4.

Rule 8 requires that the plaintiff provide "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8. A "shotgun" pleading is one that fails "to

one degree or another . . . to give the defendants adequate notice of the claims against them and the grounds upon which each claim rests." *Weiland v. Palm Beach Cnty. Sheriff's Office*, 792 F.3d 1313, 1323 (11th Cir. 2015). "A dismissal under Rule[] 8(a)(2) [. . .] is appropriate where 'it is virtually impossible to know which allegations of fact are intended to support which claim(s) for relief.'" *Id.* at 1325 (quoting *Anderson v. Dist. Bd. of Trustees of Cent. Fla. Cmty. Coll.*, 77 F.3d 364, 366 (11th Cir. 1996)). A defendant faced with a shotgun pleading should move under Rule 12(e) for a more definite statement, not seek dismissal on the grounds of alleged "shotgun" pleading issues. *See Weiland*, 792 F.3d at 1323.

Here, Plaintiffs' allegations clearly assert the grounds for relief against each Defendant and more than adequately meet the requirements of Rule 8. *See Consumer Fin. Prot. Bureau v. RD Legal Funding, LLC*, 332 F. Supp. 3d 729, 770 (S.D.N.Y. 2018). As set forth *supra* Part I.A and *infra* Part III, Plaintiffs' Complaints laboriously recount Defendants' manufacture and sale of adulterated VCDs, facts which were well known to them prior to the filing of the Complaints, and further brought to light by discovery produced to date. The Complaints leave no room for Defendants to guess what it is they are alleged to have done wrong. Quite simply, there is no legitimate question that the robust Complaints satisfy Rule 8. Defendants were given fair notice of the claims against them, which is all that Rule 8 requires. *See, e.g.*, *Wynder v. McMahon*, 360 F.3d 73, 79 (2d Cir. 2004) (noting that "[t]he key to Rule 8(a)'s requirements is whether adequate notice is given," and that "fair notice" is "that which will enable the adverse party to answer and prepare for trial, allow the application of res judicata, and identify the nature of the case so that it may be assigned the proper form of trial" (internal quotation marks omitted)); *Hudak v. Berkley Grp., Inc.*, 2014 WL 354676, at *4 (D. Conn. Jan. 23, 2014) ("Nothing in Rule 8 prohibits collectively referring to multiple defendants where the complaint alerts defendants that identical claims are asserted against each defendant."). Indeed, the very fact that Defendants at each level

(manufacturer, wholesaler, and retailer) were able to read and discern the Complaints and move to dismiss them in a targeted manner, spanning 120 collective pages of briefing between them, belies their arguments that the pleadings should be dismissed as unintelligible "shotgun" pleadings.

II. STANDARD OF REVIEW

While Defendants bring their motions to dismiss under Rules 12(b)(1) and (b)(6) (*see, e.g.*, Mfr. Br. at 7), the applicable standards of review are the same under both Rules.

A Rule 12(b)(1) standing challenge can be raised as a "facial" or "factual" attack. *See, e.g.*, *Constitution Party of Pa. v. Aichele*, 757 F.3d 347, 357 (3d Cir. 2014). A "facial" attack is essentially considered under the same standard as a Rule 12(b)(6) motion; a "factual" attack, as the name suggests, is different, as it entails review of the pertinent facts. *Id.* Defendants concede their Rule 12(b)(1) challenge is a "facial attack." *See* Mfr. Br. at 7 ("a facial challenge to standing is evaluated under the same legal standard as a Rule 12(b)(6) motion."). As such, the same Rule 12(b)(6) standard governs the entirety of Defendants' motions.

In deciding a Rule 12(b)(6) motion to dismiss, the court must view a complaint in the light most favorable to the non-moving party, and all inferences must be drawn in the non-movant's favor. *McTernan v. City of York*, 577 F.3d 521, 526 (3d Cir. 2009). At this early stage, and prior to a fully developed discovery record, the plaintiff must only allege "sufficient factual matter, accepted as true, 'to state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Plausible factual allegations "raise a right of relief above the speculative level." *Twombly*, 550 U.S. at 555. Stated otherwise, "[a] plaintiff need only put forth allegations that raise a reasonable expectation that discovery will reveal evidence of the necessary element," *Thompson v. Real Estate Mortg. Network*, 748 F.3d 142, 147 (3d Cir. 2014) (internal quotations and citation omitted), as has been done here.

"[A] complaint attacked by a . . . motion to dismiss does not need detailed factual allegations." *Twombly*, 550 U.S. at 555. On a Rule 12(b)(1) motion, "the level of specificity necessary to avoid dismissal for lack of standing should not be 'exaggerated.'" *Cottrell v. Heritages Dairy Stores, Inc.*, Civ. No. 09-1743, 2010 WL 3908567, at *3 (D.N.J. Sept. 30, 2010) (Kugler, J.) (quoting *Hosp. Council of W. Pa. v. City of Pittsburgh*, 949 F.2d 83, 86-87 (3d Cir. 1991)). Rather, "[a]t the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice, for on a motion to dismiss [courts] [p]resume that general allegations embrace those specific facts that are necessary to support the claim." *Lujan v. Defenders of Wildlife*, 504 U.S. 550, 561 (1992) (internal quotations and citation omitted). Indeed, as the Third Circuit has found, "judging the sufficiency of a pleading is a context-dependent exercise." *W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 98 (3d Cir. 2010). It is not for the Court at the Rule 12(b)(6) stage to determine the probability that a plaintiff will ultimately be successful in their claims, but rather to assess whether the plaintiff has plausibly delineated a claim within the four corners of their complaint. *In re Lipitor Antitrust Litig.,* 868 F.3d 231, 260 (3d Cir. 2017); *see also Twombly*, 550 U.S. at 570. It is also not a plaintiff's obligation, in drafting their complaint, to "plead facts that, if true, definitely rule out all possible innocent explanations." *In re Niaspan Antitrust Litig.*, 42 F.Supp.3d 735, 753 (E.D. Pa. 2014).

Further, it is important to note, any questions that require a factual determination or raise a factual controversy are not appropriate for the Court to decide at this stage. *See Hoffman-La Roche Inc. v. Genpharm Inc.,* 50 F. Supp. 2d 367, 380 (D.N.J. 1999) (Walls, J.) ("the Court cannot make such factual determinations on a factual controversy roiled by a motion to dismiss"). Legal questions that depend upon a developed factual record (such as certain inquiries raised by specific state law claims) are not properly the subject of a motion to dismiss. *See, e.g., TriState HVAC Equip., LLP v. Big Belly Solar, Inc.*, 836 F. Supp. 2d 274, 284 (E.D. Pa. 2011).

III. ARGUMENT

A. The Economic Loss and Medical Monitoring Plaintiffs Meet the Article III Standing Requirements[2]

As recently emphasized by the Third Circuit, the "[i]njury-in-fact element is not Mount Everest. The contours of the injury-in-fact requirement, while not precisely defined, are very generous, requiring only that claimant allege[] some specific, identifiable trifle of injury." *In re Horizon Healthcare Servs. Inc. Data Breach Litig.*, 846 F.3d 625, 633 (3d Cir. 2017) (citation omitted); *see also Lujan*, 504 U.S. at 560-61; *Cottrell v. Alcon Labs.*, 874 F.3d 154, 162 (3d Cir. 2017) (reversing dismissal based on lack of standing). Article III only requires a plaintiff to demonstrate an (1) injury in fact; that is (2) fairly traceable to the challenged conduct of the defendant, and that (3) is likely to be redressed by a favorable judicial decision. *Cottrell*, 874 F.3d at 162; *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016). Further, in class actions, the Article III analysis is applied to the named plaintiffs only. *See, e.g., McCray v. Fidelity Nat. Title Ins. Co.*, 682 F.3d 229, 243 (3d Cir. 2012). Defendants' various arguments that Plaintiffs (or absent class members) lack standing fail.

1. The Economic Loss and Medical Monitoring Classes Properly Allege Article III Injury-in-Fact

Economic Loss Plaintiffs and Medical Monitoring Plaintiffs each detailed, *ad nauseum*, the injury they suffered throughout the Master Complaints. Economic Loss Plaintiffs detailed how they purchased, and paid out of pocket (or reimbursed) for, VCDs that were adulterated pursuant to 21 U.S.C. § 351(a)(1) and (a)(2)(B) (and analogous state law), thus rendering them unlawful to sell, market, or distribute in the United Sates and consequently economically worthless. *See, e.g.*, ELMC ¶¶ 4, 10-34, 359, 371-72; MMMC ¶ 328. Medical Monitoring Plaintiffs ingested VCDs

[2] Defendants do not challenge Plaintiffs' standing to sue for personal injuries sustained as a result of ingesting Defendants' VCDs.

which exposed them to NDMA, resulting in cellular damage, genetic harm and/or an increased latent risk of developing cancer in the future. *See, e.g.*, MMMC ¶¶ 1, 10-19, 293, 328-329, 421, 485; *see also* ELMC ¶¶ 4, 161, 311-314, 324, 348, 350, 362. TPPs were economically injured by paying for a worthless drug option for their beneficiaries, resulting in millions of dollars in payments for a worthless product. *See, e.g.*, ELMC ¶¶ 45, 145; *see also* MMMC ¶ 328.

Defendants argue, however, that because the Economic Loss and Medical Monitoring Plaintiffs do not bring claims for physical injury (in the case of the Economic Loss Plaintiffs) or physical injury that has already resulted in cancer (in the case of the Medical Monitoring Plaintiffs), they received the product they bargained for, and therefore cannot have suffered an economic injury. *See* Mfr. Br. at 10, 12. Defendants' argument mischaracterizes the allegations and, as especially relevant in the standing inquiry, overstates and misstates what is required to show injury under Article III. *See In re Google Inc. Cookie Placement Consumer Priv. Litig.*, 806 F.3d 125, 134 (3d Cir. 2015) ("Though the injury must affect the plaintiff in a personal and individual way, this standard does not demand that a plaintiff suffer any particular type of harm to have standing.") (internal quotation and citation omitted). Standing is satisfied because Plaintiffs suffered economic harm in paying for a product that was worthless (for reasons explained below and elsewhere in this brief) and because, under these circumstances, the threat of future cancer (as alleged by the Medical Monitoring Plaintiffs) is not speculative within the meaning of the law.

a. Economic Loss Plaintiffs allege monetary Harm, which is a paradigmatic form of injury-in-fact

"Monetary harm is a classic form of injury-in-fact. Indeed, it is often assumed without discussion." *Danvers Motor Co. v. Ford Motor Co.*, 432 F.3d 286, 293 (3d Cir. 2005). Defendants do not argue otherwise. The Economic Loss Plaintiffs suffered harm that is concrete and particularized. *Cottrell*, 874 F.3d at 163 ("Typically, a plaintiff's allegations of financial harm

will easily satisfy [injury-in-fact]."). Defendants' assertion that there has been no economic injury is premature and belied by law and precedent.

b. Defendants promised a generic equivalent drug, and violated the law in not delivering that product

Plaintiffs' monetary injury resulted from Defendants' failure to provide the benefit for which Plaintiffs bargained. *See* ELMC ¶¶ 363, 428, 43, 443; MMMC ¶ 473. An injury based on a benefit-of-the-bargain theory depends on the nature of the bargain itself. *See, e.g.*, *McDonough v. Bayer Healthcare, LLC*, Civ. No. 10-442, 2011 WL 2119107, at *4 (D.N.J. May 26, 2011) (Martini, J.) (analyzing whether defendants' promises regarding the quality of a pesticide and its impact on animals formed the basis of the bargain to constitute an express warranty); *In re Ford Motor Co. E-350 Prods. Liab. Litig.*, MDL No. 1687, 2008 WL 4126264, at *4-5 (D.N.J. Sep. 2, 2008) (Ackerman, J.) (examining nature of the bargain and plaintiffs' reliance thereon before looking to existence of warranty and benefit of the bargain analysis). Here, Plaintiffs allege as follows: in return for the purchase price paid to Defendants, Plaintiffs would benefit from the generic equivalent of Diovan; a pure, unadulterated, and regulatory compliant valsartan generic drug, which would be identical to brand-name valsartan (Diovan or Exforge). *See, e.g.*, ELMC ¶¶ 351-366; MMMC ¶¶ 318-332.

Defendants argue that because Plaintiffs do not allege that they have been physically harmed by Defendants' VCDs, they received what they bargained for. *See* Mfr. Br. at 11-12. This characterization is incorrect. Aside from the expected therapeutic bioequivalence, Plaintiffs purchased Defendants' VCDs based on Defendants' representations and warranties that their VCDs were bioequivalent to Diovan and Exforge, and that they were non-adulterated (e.g., non-contaminated and originating from cGMP compliant manufacturing facilities or processes). *See, e.g.*, ELMC ¶¶ 144, 356, 361-75, 381, 391; MMMC ¶¶ 318-332 (discussing assurances made by

Defendants that their VCDs were compliant with cGMPs and equivalent to Diovan); ELMC ¶¶ 369, 372, 377, 385, 387, 442; MMMC ¶ 473 (alleging and describing the nature of the bargain). Defendants omitted material information that these representations were false, and that their products were not the generic equivalent, and neither pure, unadulterated, nor cGMP compliant. These omissions induced Plaintiffs' actions and reliance at purchase, and harmed plaintiffs upon discovery that the VCDs were worthless. *See* ELMC ¶¶ 168-174, 484, 497, 514; MMMC ¶¶ 130-136, 322, 422. The value of Defendants' generic product is entirely predicated on its being the same as the brand product, which it was not. Defendants' VCDs are worthless to Plaintiffs, as the Eleventh Circuit determined in the *Debernardis v. IQ Formulations, LLC* case. 942 F.3d 1076 (11th Cir. 2019). In that case, the Eleventh Circuit found standing, and also accepted the plaintiff's theory that a product that was illegal to sell under Federal Food Drug and Cosmetics Act ("FDCA") was economically worthless because Congress essentially legislated as much by making adulterated drugs illegal to commercialize in the United States.

Plaintiffs acted and relied on Defendants' assurances in their labeling and their marketing, and bargained for the quality control and purity promised to them when they purchased VCDs. "For each consumer who relies on the truth and accuracy of a label . . .the economic harm is the same: the consumer has purchased a product that he or she *paid more* for than he or she otherwise might have been willing to pay[.]" *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Practices and Liab. Litig.*, (hereinafter *Estrada*), 903 F.3d 278, 290 n.14 (3d Cir. 2018) (emphasis added) (internal quotations and citation omitted).

In addition to affirmatively misrepresenting the quality, regulatory compliance, and safety of their VCDs, Defendants omitted material information that induced Plaintiffs to act and rely on Defendants' assurances and purchase VCDs. These omissions also caused Plaintiffs' economic and physical harm. For example, Defendants materially omitted that their manufacturing facilities

or processes were not cGMP compliant. *See* ELMC ¶¶ 172-173, 508-520; MMMC ¶¶ 134-135.

Plaintiffs paid for VCDs because they were assured that they were equivalent to Diovan and Exforge, and the omission of the true facts was material. Because the products Plaintiffs purchased were adulterated and non-compliant with cGMPs, they were also illegal to sell in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B). As in *Blue Cross Blue Shield Assoc. v. GlaxoSmithKline LLC*, 417 F. Supp. 3d 531 (E.D. Pa. 2019), discussed *infra* Part III.A.1.a, Plaintiffs have alleged that the VCDs were not generic equivalents, adulterated and non-compliant with cGMPs, and are worthless to them. *See, e.g.*, ELMC 121 ¶ 362; MMMC ¶ 328. They did not get what they bargained for, and were harmed as a result.

When courts in this District previously considered the benefit-of-the-bargain theory that Plaintiffs put forward here they have found the plaintiffs had more than sufficiently alleged injury-in-fact. In *In re Gerber Probiotic Sales Practices Litig.*, No. 12-835, 2013 WL 4517994 (D.N.J. Aug. 23, 2013) (Linares, J.), the plaintiffs purchased defendants' baby formula relying on representations that the baby formula was nearly identical in quality and immune system benefits to breast milk, but the formula provided no such benefits.

However, the defendants argued that the baby formula still provided benefits to purchasers, and that no child suffered any ill effects from the product. The court rejected this argument, because it was "not the substance of Plaintiffs' claim." *Id.* at *5. Rather, the basis of the bargain was that plaintiffs paid for baby formula with the qualities the defendants promised them, and instead received a worthless product. *See id.*; *see also In re Mercedes-Benz Emissions Litig.*, No. 16-881, 2019 WL 413541 (D.N.J. Feb. 1, 2019) (Linares, J.) (finding injury-in-fact where plaintiffs purchased vehicles based on defendants' assurances that they were more fuel-efficient than other cars), *vacated in part on other grounds*, 797 Fed. App'x 695 (3d Cir. Jan. 10, 2020) (addressing narrow issue pertaining to arbitration only).

A sister district court's opinion in *Blue Cross* is also instructive here. In that case, third-party payor plaintiffs sought damages because they purchased a drug that defendants warranted as compliant with cGMPs. *See Blue Cross Blue Shield Assoc. v. GlaxoSmithKline LLC*, 417 F. Supp. 3d 531 (E.D. Pa. 2019). Instead, plaintiffs received drugs from manufacturing plants that had been forced to issue recalls by the FDA due to non-compliance with cGMP standards. *Id.* at 554. Defendants in *Blue Cross* brought identical arguments to those that Defendants raise in this case – that the cGMP violations did not have an impact on the drug itself. The court held that non-compliance with cGMPs could plausibly have rendered the products at issue worthless to plaintiffs, and that was a sufficient injury to confer standing. *Id.* at 554-55. Notably, the *Blue Cross* case proceeded to trial, where a judgment was entered in the third-party payors' favor. *See also Debernardis*, 942 F.3d at 1084-85 (accepting plaintiff's contention that adulterated supplements are economically worthless).

The foregoing applies equally both to consumer class members as well as TPP class members. *See, e.g.*, *In re Warfarin Sodium Antitrust Litigation*, 391 F.3d 516, 531 (3d Cir. 2004) (TPP has standing to sue drug manufacturer for their misrepresentations when it results in the insurance company's payment of inflated prices for drug); *Blue Cross Blue Shield*, 417 F. Supp. 3d 531 (E.D. Pa. 2019) (TPPs had standing to sue manufacturer for cGMP violations); *Am. Fed'n of State Cty. & Mun. Employees v. Ortho-McNeil-Janssen Pharm., Inc.*, No. 08-CV-5904, 2010 WL 891150, at *3 (E.D. Pa. Mar. 11, 2010) (TPPs adequately alleged injury in fact for the costs they have paid or will pay to replace defective prescription Fentanyl patches)*; In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517, 543 (D.N.J. 2004) (Greenaway, J.) (holding that third-party payors suffered an injury-in-fact for standing purposes).

Completely ignoring the on-point relevant cases, Defendants primarily rely on the *Estrada* ruling, but that case is distinguishable on its merits. In *Estrada*, prior to appeal, the district court

theorized two specific categories under which plaintiffs could properly allege an Article III injury in fact: if "(i) the plaintiffs received a defective product; or (ii) the plaintiffs pled facts sufficient for the court to conclude that they would not have purchased the product at issue but for a specific misrepresentation made by the defendants." *Estrada v. Johnson & Johnson*, No. 16-7492, 2017 WL 2999026, at *9 (D.N.J. July 14, 2017) (Wolfson, J.); *see In re Mercedes-Benz*, 2019 WL 413541 at *4 (discussing benefit-of-the-bargain categories discussed in *Estrada*, where standing is recognized). The Third Circuit relied on this reasoning in its decision in affirming *Estrada*—plaintiff Estrada failed to allege that the baby powder she purchased did not provide what she bargained for, and that she would not have paid for it if informed, and therefore failed to plead injury-in-fact. *Estrada*, 903 F.3d at 288.

Unlike those in *Estrada*, Plaintiffs' allegations fall squarely into the second category contemplated by the Third Circuit: Plaintiffs have pled facts that show that they purchased VCDs based on Defendants' representations and material omissions and assurances of quality control and purity. *See* MMMC ¶¶ 298-302, 318-332, 342, 345, 486-489; ELMC ¶¶ 227, 244, 331, 335, 375-376, 379, 385-387. Plaintiffs' allegations show that their bargained-for benefit was a generic drug that Defendants assured them was identical to Diovan or Exforge and of equivalent quality and manufacturing standards. Plaintiffs additionally plead, in contrast to the plaintiff in *Estrada*, that Defendants' VCDs are worthless to them. *Compare* ELMC ¶ 362 (pleading that Defendants' VCDs are worthless), MMMC ¶ 328 (same), *with Estrada*, 903 F.3d at 288 (noting that plaintiff did not allege that the baby powder product was worth less than what she paid).[3] While Defendants

[3] The remaining cases that Defendants cite in support of their argument are similarly distinguishable. Defendants cite *Koronthaly* (an unpublished decision that is not binding precedent) in support of their argument that absent a physical injury or allegations that the VCDs were therapeutically ineffective, the VCDs cannot be worthless. *Koronthaly v. L'Oreal USA, Inc.*, 374 Fed. App'x 257, 259 (3d Cir. 2010). This argument elides the important nuance that whether

are entitled to raise the factual questions associated with their benefit of the bargain theory, these questions are *factual* in nature, and consequently inappropriate for dismissal at the 12(b)(6) stage. *See also Debernardis*, 942 F.3d at 1084-85 (accepting plaintiff's contention that adulterated supplements are economically worthless).

c. At the pleading stage, Plaintiffs are not required to provide an exact value of their injuries

Finally, Defendants argue that Economic Loss Plaintiffs cannot value their injuries, and therefore cannot plead injury-in-fact. At the outset, Plaintiffs are not required to "allege the *exact* value of [their] economic injury at the pleading stage," as this occurs later in the litigation. *Estrada*, 903 F.3d at 287 (emphasis in original). Moreover, Plaintiffs have alleged that the VCDs they purchased were *worthless* (zero value) and federal courts have accepted such allegations both at the pleading stage (*Debernardis*) and at the expert evidence and trial phases (*Blue Cross Blue Shield*). As courts have found, "valuations do not have to be perfect…[t]hey need only provide a reasonable basis for valuation that is not speculative or unquantified." *Smajlaj v. Campbell Soup Co.,* 782 F. Supp. 2d 84, 102–03 (D.N.J. 2011) (Simandle, J.). In their ELMC, Plaintiffs have provided a more than reasonable basis for determining that the value of the VCDs adulterated with NDMA or other nitrosamines is zero. *See, e.g.*, *Blue Cross Blue Shield Ass'n v. GlaxoSmithKline*,

---

a bargain's benefit is received depends on what is being bargained *for*. In *Koronthaly*, the plaintiff failed to allege that the product she purchased was worth less to her than what could be reasonably expected. *Koronthaly,* 374 Fed. App'x 257, 259 (3d Cir. 2010). In contrast, here, Plaintiffs do not allege mere buyer's remorse; nor did they only bargained for a therapeutically effective generic drug (but rather, one that was not adulterated or misbranded). Thus, it is not just the adulteration by itself that forms the basis of Plaintiffs' claims (which would be sufficient in itself for Rule 12 purposes), but rather the fact that Plaintiffs' purchased Defendants' VCDs *because* they were promised a pure and regulatory compliant product that was equivalent to Diovan or Exforge. Because Defendants failed to deliver on their end of the bargain, and supplied an adulterated and non-compliant product, Plaintiffs did not receive any benefit for what they paid. That the VCDs may or may not be therapeutically effective does not control because it is only one component of the bargain.

No. 13-4663, 2019 WL 4751883, at *1, *8-9 (E.D. Pa. Sept. 30, 2019) (denying *Daubert* motion as to third-party payors plaintiffs' damages expert opinion that non-CGMP compliant drugs were worthless); *see also Debernardis*, 942 F.3d at 1084-85 (accepting plaintiff's contention that adulterated supplements are economically worthless).

d. Medical Monitoring Plaintiffs allege physical and monetary harm, satisfying Article III injury-in-fact

Medical Monitoring Plaintiffs likewise meet the requirements for injury-in-fact for all the same reasons described above as to Economic Loss Plaintiffs. The Medical Monitoring Plaintiffs allege economic harm under a benefit of the bargain theory, which by itself is sufficient to meet Article III's requirements. *See* MMMC ¶ 473 (describing basis of the bargain); *id.* ¶¶ 405, 413, 429 (seeking compensatory damages); *id.* p.146 § 6 (Prayer for Relief seeking monetary relief),

Defendants contend that the Medical Monitoring Plaintiffs allege only a speculative harm. This argument is without merit. The Third Circuit has unequivocally determined that, in medical monitoring cases, exposure to contaminated products or a medical device with a risk of failure constitutes an injury-in-fact. *See Reilly v. Ceridian Corp.*, 664 F.3d 38, 45 (3d Cir. 2011) (noting that medical monitoring claims are a carve-out exception to the general rule of rejecting standing based on future harm). Medical monitoring claims are a recognized exception to the concerns of speculative or future harm that Defendants have. *Id.*; s*ee also Player v. Motiva Enters., LLC*, No. 02-3216, 2006 WL 166452, at *9 (D.N.J. Jan. 20, 2006) (Kugler, J.) (holding that medical monitoring claims are appropriate where a plaintiff "exhibits no physical injury, but nevertheless requires medical testing as a proximate result of defendant's. . .conduct."); *Fried v. Sungard Recovery Servs.*, 925 F. Supp. 375, 377 (E.D. Pa. 1996) (holding that "need for medical monitoring is an injury" for standing purposes).

In support of their argument, Defendants merely rely on two inapposite cases – and notably

neither of which involved medical monitoring claims. *See James v. Johnson & Johnson Consumer Cos., Inc.*, No. 10-3049, 2011 WL 198026, at *2 (D.N.J. Jan. 20, 2011) (Cavanaugh, J.) (discussing future injury outside medical monitoring context); *Hubert v. Gen. Nutrition Corp.*, No. 15-1931, 2017 WL 3971912, at *9 (W.D. Pa. Sep. 8, 2017) (same). In short, the Medical Monitoring Plaintiffs adequately allege injury-in-fact.

2. Plaintiffs' Injuries Are Traceable to Defendants

"[T]he traceability prong focuses on *who* inflicted [] harm." *In re Mercedes-Benz*, 2016 WL 7106020, at *6 (emphasis original) (citing *Toll Bros., Inc. v. Twp. of Readington*, 555 F.3d 131, 142 (3d Cir. 2009)). Importantly, an "indirect causal relationship will suffice." *Pitt News v. Fisher*, 215 F.3d 354, 360 (3d Cir. 2000). Manufacturer Defendants argue that Plaintiffs' injuries are not traceable to each and every Defendant, and are therefore not traceable at all, *see* Mfr. Br. at 15-16;[4] Wholesaler Defendants argue that Plaintiffs injuries are not traceable to them because they did not manufacture or design the VCDs. *See* Wholesaler Br. at 9. These arguments are without merit. The Retail Pharmacy Defendants do not challenge any standing.

a. Manufacturer Defendants

Plaintiffs satisfy the traceability prong by pleading facts that show how Manufacturer Defendants' assurances and representations were part of the bargain underlying their purchases of VCDs. *See, e.g.*, *In re Mercedes-Benz*, 2016 WL 7106020, at *8 (explaining that harm could be

[4] Defendants' assertion that there is no plaintiff who has alleged claims against certain finished dose Manufacturer Defendants, Retail Pharmacy Defendants, or Repackager/Relabeler Defendants, *see* Mfr. Br. at 10-11, is for another day. Plaintiffs will address this argument by the proposed addition, under Federal Rules of Civil Procedure 15, 21 and 23, of additional plaintiffs at the appropriate time as necessary. It is not even necessary for a class to have a representative against every defendant. *See, e.g.*, *In re Asacol Antitrust Litig.*, 907 F.3d 42 (1st Cir. 2018) (named plaintiffs in certain states had standing to assert claims on behalf of absent class members in other states). To the extent necessary, these additional plaintiffs can bring direct claims against any other Defendant, curing any alleged defect raised by Defendants. As to Wholesaler Defendants listed in Manufacturer Defendants' Charts, *see* ECF 520-5 at 10-11, Plaintiffs properly bring claims against Wholesaler Defendants as explained herein.

fairly traceable to defendants' representations in advertisements); *In re Gerber*, 2013 WL 4517994, at *10 (noting that plaintiffs' injuries were fairly traceable to the assurances defendants made on the product label). Plaintiffs have alleged sufficient facts that demonstrate the causal link between their injuries and the conduct of all Defendants.

Both Economic Loss and Medical Monitoring Plaintiffs' injuries are traceable to the conduct of Manufacturer Defendants. Manufacturer Defendants are the makers of the VCDs and/or the valsartan API within the VCDs, and made the assurances and representations of quality and cGMP compliance that induced Plaintiffs' purchase of these products. *See, e.g.*, *Carlough v. Amchem Prods., Inc.*, 834 F. Supp. 1437, 1455 (E.D. Pa. 1993) (finding traceability prong met). Plaintiffs have also pleaded sufficient facts that they expected and bargained for Defendants' assured quality control and product purity, establishing a link between Plaintiffs' injuries and Defendants' conduct.

b. Wholesaler Defendants

Traceability is satisfied as to the Wholesaler Defendants because the Wholesaler Defendants control virtually all of the supply and wholesale market for VCDs, and therefore all or nearly all Plaintiffs purchased VCDs that were supplied by one or more of the named Wholesaler Defendants.

As an initial matter, Plaintiffs allege that the three major wholesalers are responsible for supplying Defendants' VCDs to retail pharmacies across the nation, and comprise over 90% of the wholesale market.[5] *See* ELMC ¶¶ 109-110, ¶¶ 175-178; MMMC ¶¶ 89, 137-140. While this

[5] These are Defendants AmerisourceBergen Corporation, Cardinal Health, Inc., and McKesson Corporation. If the Wholesaler Defendants contend they do not comprise a majority share of the market, they are free to deny the allegations in the Complaints. However, it is not for the Court to decide whether they do or do not comprise a majority of the market share, but rather to decide whether Plaintiffs have plausibly plead that they do. Plaintiffs have done precisely that.

Circuit has yet to rule squarely on the issue of whether market share is sufficient to satisfy traceability, the facts of the *Cottrell* case are persuasive. In *Cottrell*, the plaintiffs' complaint named only two distributors[6] of the product at issue, indicating a market structure similar to that here, where a small number of distributors dominate the supply chain. *Compare, e.g.*, ELMC ¶¶ 42-44, ¶¶ 57-59, *with Compl.*, *Cottrell v. Alcon Labs., Inc.*, No. 14-05859 (D.N.J. Sep. 18, 2014). The Third Circuit found that the *Cottrell* plaintiffs had established Article III standing to sue on their consumer protection claims against *both* the manufacturers and distributors of eye drop medication. *Cottrell*, 874 F.3d at 171.

Persuasive analysis is also available from the Eleventh Circuit, which squarely held that an injury could be fairly traced to a distributor when the market is dominated by a limited number of distributors. *Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076 (11th Cir. 2019). In *Debernardis*, plaintiffs brought consumer claims against manufacturers and distributors of a dietary supplement that was adulterated with a contaminant and therefore illegal to sell. The distributor defendants argued that the claimed injury was not traceable to their conduct because they exercised no control over the manufacturers, did not design the supplements themselves, and because plaintiffs did not show that they purchased contaminated supplements from distributor defendants' supply. *Id.* at 1088. The Eleventh Circuit rejected this argument because "the complaint alleged that only two entities supplied the supplements to consumers" via several retailers. *Id.* Because the distributor defendants were the "sole distributor[s] that supplied supplements . . .only [they] could have provided the supplements the plaintiffs bought." *Id.* at 1089.

Wholesaler Defendants make an identical argument here, arguing that because of their

[6] The terms wholesaler and distributer are used interchangeably in various cases.

"unique position in the supply chain," they are too remote from Plaintiffs' injury. *See* Wholesaler Br. at 8. In fact, it is precisely that "unique position" – the named Wholesaler Defendants represent the three major distributors of VCDs – that links Plaintiffs' injuries with Wholesaler Defendants' conduct. The VCDs that Plaintiffs purchased could only have come from Wholesaler Defendants, with virtually no exceptions. As in *Debernardis* and *Cottrell*, here too Wholesaler Defendants are the "sole distributor[s] that supplied [VCDs]" to Retail Pharmacy Defendants, and therefore only Wholesaler Defendants "could have provided the [VCDs]" the Plaintiffs bought. *Debernardis*, 942 F.3d at 1089.

Wholesaler Defendants' other traceability arguments also fail. *First*, Plaintiffs are not required to plead "but-for" causation for the standing inquiry, as Wholesaler Defendants suggest. *See* Wholesaler Br. at 8 (arguing that Plaintiffs needed to show but-for causation). The teachings of this Court and this Circuit clarify that while the fairly traceable prong is *akin* to "but for causation in tort," the prong may be satisfied "even where the conduct in question might not have been a proximate cause of the harm." *Seniors Benefit Res. v. New Jersey Dep't of Human Servs.*, 2018 WL 555244, at *5 (D.N.J. Jan. 25, 2018) (Martinotti, J.) (internal quotations and citation omitted). Ultimately, the "fairly traceable requirement . . .is not equivalent to a requirement of tort causation." *Interfaith Community Org. v. Honeywell Intern., Inc.*, 399 F.3d 248, 257 (3d Cir. 2005) (internal citation and quotation omitted) (finding plaintiffs' economic injuries and statutory injury as to potential health consequences were fairly traceable to defendants' chemical waste dumping).

Second, Wholesaler Defendants' argument that they did not "design, formulate or manufacture VCDs," Wholesaler Br. at 9, does not break the causal link between their conduct and Plaintiffs' injuries, and is irrelevant to it. Plaintiffs' allegations center on the assurances and warranties provided by Wholesaler Defendants, as well as their dominance of the wholesale market

for generic valsartan. *See, e.g.*, ELMC ¶¶ 175-178, 402; MMMC ¶¶ 89, 368-376 (pleading facts related to warranties and assurances made by Wholesaler Defendants and breach thereof).

In *In re National Prescription Opiate Litigation*, the same distributor defendants as those here argued that because they did not manufacture the opioids at issue, they were too far removed from plaintiffs' economic injuries. 440 F.Supp.3d 773, 811 (N.D. Ohio 2020). The MDL court rejected that argument, because plaintiffs included allegations that distributors breached their duties to plaintiffs, as it related to investigating suspect opioid products. *Id.* Here, Plaintiffs' allegations are similar to those in the opioid litigation, and adequately demonstrate the link between Wholesaler Defendants' conduct and Plaintiffs' injuries.

Plaintiffs plead facts that Wholesaler Defendants independently breached both warranties and duties under the Drug Supply Chain Security Act ("DSCSA"), 21 U.S.C. § 353, *et seq.* and state common law, regardless of and independent from Manufacturer Defendants' conduct. Plaintiffs allege that all three Wholesaler Defendants made warranties or representations to Plaintiffs that they will engage in "fair dealing"; that they comply with regulatory requirements; and that the VCDs they distribute are equivalent to Diovan or Exforge. *See, e.g.*, MMMC ¶ 123, ¶¶ 368-374. Wholesaler Defendants' reliance on *Sherfey* and *Moore* is misplaced, as both cases are completely distinguishable and predate Wholesaler Defendants' statutory and more recent common law obligations.[7]

[7] The complaints in both *Sherfey* and *Moore* were filed prior to the enactment of the Drug Supply Chain Security Act, and thus these cases do not properly address the obligations Wholesaler Defendants face in this case. *See Moore v. Johnson & Johnson*, 907 F.Supp.2d 646, 651 (E.D. Pa. 2012) (describing procedural history); *Sherfey v. Johnson & Johnson*, 2012 WL 3550037, at *1 (Ed. Pa. Aug. 17, 2012) (describing procedural history). Additionally, the plaintiffs in *Sherfey* and *Moore* did not allege any violation of federal statutory duty. *See Sherfey*, No. 12-4162, 2014 WL 1663966, at *1 (listing common law and state law causes of action); *Moore*, 83 F. Supp. 3d at 630 (listing consumer protection and civil conspiracy causes of action). Here, Plaintiffs allege that Defendants had obligations under the Drug Supply Chain Security Act, *see* ELMC ¶¶ 401, 402,

Wholesaler Defendants cite no authority to support their argument that they have no duty to, nor are they even capable of, testing the products they distribute. *See* Wholesaler Br. at 9; *cf*. *In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig.*, 97 F.3d 1050 (8th Cir. 1996) (relied on by defendants and predating the DSCSA by nearly two decades). However, this is a myopic reading of the DSCSA. As discussed more fully *infra* at Part III.B, the DSCSA, in concert with the FDCA, requires wholesalers and retailers not to place adulterated and/or misbranded drugs into the drug supply chain. State law similarly imposes parallel common law duties. Even assuming no such obligation exists to ensure that they are not placing drugs that are adulterated or misbranded into the drug supply chain, this is a merits defense suitable for adjudication after discovery.

Additionally, Wholesaler Defendants read the Master Complaints too narrowly. Plaintiffs do not allege Wholesaler Defendants only had a duty to "test," but rather allege Wholesaler Defendants had a broader duty to exercise reasonable care to investigate and inspect products and the manufacturing sources of products for adulteration, and to implement systems and practices to identify and to investigate suspect products or illegitimate products. *See* ELMC ¶¶ 401, 402, 404; MMMC ¶¶ 368, 378, 380. That duty is rooted in federal law and non-conflicting state common law. Plaintiffs have further alleged that Wholesaler Defendants made warranties and representations as to the quality and purity of the VCDs, and breached these warranties through their independent conduct. *See, e.g.*, ELMC ¶ 466; MMMC ¶ 443. Indeed, Wholesaler Defendants effectively concede their obligations, at least under the Drug Supply Chain Security Act, by arguing preemption. *See* Wholesaler Br. at 10.

404; MMMC ¶¶ 368, 378, 380, and allege violations of the Magnuson-Moss Warranty Act, *see* ELMC ¶ 466; MMMC ¶ 443, and state law.

3. Plaintiffs May Properly Bring Claims on Behalf of Out-of-State Putative Class Members

The Third Circuit has held that so long as the named plaintiff in a class action can establish standing, putative class members need not establish Article III standing. "We now squarely hold that unnamed, putative class members need not establish Article III standing. Instead, the 'cases or controversies' requirement is satisfied so long as a class representative has standing, whether in the context of a settlement or litigation class." *Neale v. Volvo Cars of North Am., LLC*, 794 F.3d 353, 362 (3d Cir. 2015).

The Third Circuit has further instructed that Rule 23 certification issues, such as adequacy, should not be prematurely embedded into the Article III standing analysis. *Mielo v. Steak n' Shake Operations, Inc.*, 897 F.3d 467 (3d Cir. 2018). In *Mielo*, the Court rejected the argument that named plaintiffs did not have standing to sue on behalf of putative class members who experienced alleged ADA violations in defendant's restaurant branches outside the forum state. *Id.* at 479. Courts in this Circuit also have considered and adopted the Second Circuit's reasoning in *Langan*, which held, as relevant to Defendants' specific argument here, that "whether a plaintiff can bring a class action under the state laws of multiple states is a question of predominance under Rule 23(b)(3), not a question of standing under Article III." *Langan v. Johnson & Johnson Consumer Cos., Inc.*, 897 F.3d 88, 96 (2d Cir. 2018).

This district court's holding in *Rolland*, which applies the *Langan* analysis, is also on all fours with this case. In *Rolland*, defendants made the identical argument that class representatives lacked standing to bring nationwide class claims under various states' laws on behalf of putative out-of-state class members. *Rolland v. Spark Energy LLC*, No. 17-2680, 2019 WL 1903990, at *5 n. 6 (D.N.J. Apr. 29, 2019) (Shipp, J.). This district court rejected the argument as "unpersuasive." *Id.* (denying motion to dismiss). Other courts in the Third Circuit have held similarly. *See, e.g.*, *Gress v. Freedom Mortg. Corp.*, 386 F. Supp. 3d 455, 462 (M.D. Pa. 2019) (denying motion to

dismiss because "Plaintiffs' capacity to state claims under the laws of other states on behalf of putative class members . . .is a matter to be decided under the rubric of Rule 23, not constitutional standing under Article III.")

Here, Plaintiffs bring claims on behalf of themselves, for which they have standing, and therefore satisfy the Article III requirements. Having demonstrated Article III standing as to the named Plaintiffs, there is "'no further separate class standing requirement in the constitutional sense.'" *In re Prudential Ins. Co. Am. Sales Practice Litig. Agent Actions*, 148 F.3d 283, 307 (3d Cir. 1998) (quoting *Newberg on Class Actions* § 2.05 at 2-9 (3d ed. 1992)). Plaintiffs have properly brought claims under various states' laws on behalf of putative class members. Any issues as to predominance, adequacy, or typicality should be addressed by the Court at the class certification stage.

B. Plaintiffs' Claims Are Not Preempted

First, preemption should not be addressed on a motion to dismiss. "Preemption is an affirmative defense, pleadings need not anticipate or attempt to circumvent affirmative defenses. . . This is why a motion to dismiss for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6) is not the appropriate vehicle for a preemption challenge: affirmative defenses typically turn on facts not before the court at [the dismissal] stage." *Laverty v. Smith & Nephew, Inc.*, 197 F. Supp. 3d 1026, 1029 (N.D. Ill. 2016) (citations omitted); *see also In re Asbestos Prods. Liab. Litig. (No. VI)*, No. 822 F.3d 125, 133 n.6 (3d Cir. 2016). Thus, dismissal is appropriate under Rule 12(b)(6) only when "preemption is manifest in the complaint itself." *See, e.g.*, *Lupian v. Joseph Cory Holdings LLC*, 905 F.3d 127, 134 (3d Cir. 2018) (affirming denial of motion to dismiss on basis of preemption).

In addition, because there is a presumption against preemption, it can only be applied where preemption was "the clear and manifest purpose of Congress." *Medtronic, Inc. v. Lohr,* 518 U.S.

470, 485 (1996); *Wyeth v. Levine*, 555 U.S. 555, 565 (2009). Congress could not have intended to preempt the claims here, where the drug in question was contaminated with a probable human carcinogen that was never approved by the FDA, let alone disclosed or made known to the public.

1. Impossibility Preemption Is Inapplicable

Defendants assert impossibility preemption in two footnotes. *See* Mfr. Br. at 24 n.22, 38-39, n.35. This is insufficient to meet Defendants' burden, especially with regard to an affirmative defense. As recognized recently in this District, "impossibility preemption is a demanding defense rather than a pleading requirement...[that] places the burden on Defendants – and not Plaintiff – to support that defense with 'clear evidence . . .'" *Gremo v. Bayer Corp.*, 2020 WL 3496917 at *6 (D.N.J. June 29, 2020) (Hillman, J.) (denying motion to dismiss design and warning claims under NJPLA, as well as express warranty claim and punitive damages claim); *see Wyeth v. Levine*, 555 U.S. 555, 573 (2009). Here, there is no impossibility, as Defendants could have easily complied with the parallel state and federal requirements. Defendants could have manufactured the approved, uncontaminated valsartan, just as other pharmaceutical drug manufacturers did. It was likewise not impossible for Defendants to comply with the cGMPs which required quality assurance and quality control measures that would have uncovered the contamination long before August 2018. One pharmaceutical manufacturer's ability to identify the contamination through quality assurance and quality control infrastructure is precisely why the contamination was even unearthed in the first place. Had Defendants done what other pharmaceutical manufacturers were obviously able to do, this would have eliminated the design and manufacturing defects, rendered the statements listing the ingredients accurate, and dispensed with the need for the manufacturers to disclose that the drugs were contaminated – which triggered the recall of the drugs and an import alert.

The very basis for preemption in the context of generic drugs is the approval, based on the drug's "equivalence to a reference listed drug that has already been approved by the FDA." *Pliva, Inc. v. Mensing*, 564 U.S. 604, 612 (2011). "[T]he proposed generic drug must be **chemically equivalent** to the approved brand-name drug . . . ." *Mutual Pharmaceutical Co., Inc.*, *v. Bartlett*, 570 U.S. 472, 477 (2013) (emphasis added). The Supreme Court has defined a generic drug as, "a drug designed to be a **copy** of a reference listed drug (typically a brand name drug) and thus **identical** in active ingredients, safety, and efficacy." *Mensing*, 564 U.S. at 612, n.2 (emphasis added).[8] Here, Defendants' VCDs were not the equivalent, a copy, or identical to the reference listed drug, since they were contaminated with NDMA or other nitrosamines, so the affirmative defense of preemption is inapplicable by definition.

In fact, Defendants were required to stop selling the contaminated valsartan, because, "[o]nce a drug – whether generic or brand-name – is approved, the manufacturer is prohibited from making major changes to the qualitative or quantitative formulation of the drug product..." *Bartlett*, 570 U.S. at 570.[9] Accordingly, when the contamination was disclosed to the FDA, the result was a recall. *See, e.g.*, *Lefaivre v. KV Pharm Co.*, 636 F.3d 935, 944 (8th Cir. 2011) (finding no preemption where the defendant "manufactured 'adulterated' medication in violation of cGMP requirements," and "issued a recall for all stocks of the medication sold to retailers"); *see also In re MDL 2700 Genentech Herceptin (Trastuzumab) Mktg. & Sales Prac. Litig.*, 960 F.3d 1210, 1240 (10th Cir. 2020) (concluding that the defendant "failed to satisfy its burden of establishing

[8] In *Mensing* the Supreme Court found that failure to warn claims alleging inadequacy of the generic drug's warnings were preempted since the generic manufacturer could not unilaterally change the warning. Of course, in that case the drug was not contaminated with a carcinogen and was the generic equivalent of the reference listed drug.

[9] This is completely different from *Bartlett*, where the drug at issue was the approved generic equivalent of the brand drug.

that impossibility pre-emption applies to plaintiffs' claim," where the defendant had previously manufactured the drug as plaintiffs alleged was required).

2. Implied Preemption Is Inapplicable

Defendants invoke implied preemption, citing to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). Defendants variously identify the claims targeted by this affirmative defense: negligence, negligence *per se*, design defect, strict liability, breach of express warranty, negligent misstatement, consumer protection, and fraud claims.[10] Mfr. Br. at 19-26.

Implied preemption is a narrow defense. The Supreme Court has defined implied preemption to focus essentially on "**fraud-on-the-FDA claims**," which are not made here. *Buckman*, 531 U.S. at 348 (emphasis added). Defendants concede that implied preemption only applies, "if the state-law claim depends on concepts or standards that exist "**solely**" because of the FDCA, [and] it does not flow from a pre-existing state-law duty...." Mfr. Br. at 19 (emphasis added) (citing *Buckman*, 531 U.S. at 352-353); *see also Yocham v. Novartis Pharms. Corp.*, 736 F. Supp. 2d 875, 885 (D.N.J. 2010) (Simandle, J.) (explaining that "the only way to make sense of the concern in *Buckman* is to understand it to be about the unique increase in incentive created by a tort in which the **sole** conduct element was such misrepresentation to the FDA") (emphasis added).

Here, Plaintiffs' claims have an independent state law basis, and Plaintiffs explicitly do not seek to enforce FDA regulations as the sole basis for recovery. The PIMC, for instance, explicitly states at Paragraph 22: "Plaintiffs reference federal law herein not in any attempt to enforce it, but only to demonstrate that their state-law tort claims do not impose any additional obligations on Defendants, beyond what is already required of them under federal law." PIMC ¶ 22; *see also*

[10] Defendants concede that they do not seek implied preemption of the breach of implied warranty, strict liability, failure to warn and manufacturing defect claims, but nonetheless include argument as to those causes of action in this section. Mfr. Br. at 27.

ELMC ¶ 176; MMMC ¶ 129. The ELMC alleges that "by referring to their drugs as 'valsartan' or 'valsartan HCT' or 'amlodipine-valsartan' or 'amlodipine-valsartan HCT' Defendants were making false statements regarding their VCDs." ELMC ¶ 182; *see also id.* ELMC ¶¶ 6, 336-37, 348, 368, 372, 378-79, 386-87, 390, 393, 395, 396, 401-02, 407-08, 412, 441, 445, 451, 454, 457-60, 462-65, 468-471, 473-74. The PIMC alleges that "Defendants negligently, carelessly, and/or recklessly manufactured, marketed, advertised, promoted, sold, designed and/or distributed the VCDs ingested by Plaintiffs as safe and effective treatment for Plaintiffs' underlying conditions." PIMC ¶ 413; *see also id.* ¶¶ 167-68, 352, 355, 358-59, 366-67, 369, 371-72, 374, 380-81, 383, 386, 389, 392, 394-98, 399-401, 414-420, 424-427,439, 441-46, 448-49. The MMMC states that "[e]ach Defendant owed a duty to Plaintiffs and the Classes to use and exercise reasonable and due care in the manufacturing, testing, distribution, labeling, marketing, warnings, disclosures, and sale of its VCDs." MMMC ¶ 395; *see also id.* ¶¶ 134, 289-90, 293-95, 306, 325, 329, 335-36, 338, 343-44, 346-47, 349, 351-52, 357-58, 360, 363, 365, 372, 373, 376, 377, 379, 398-405, 415-429, 431-436, 438-442.

A recent New Jersey Supreme Court case is instructive. In *In re Reglan Litigation*, 226 N.J. 315 (2016), generic manufacturers failed to utilize the label approved by the FDA for the brand name product. The Court found the failure to warn claim was not preempted, observing that "[a] violation of the FDCA's sameness requirements is not an element of plaintiffs' claims. Plaintiffs' claims do not exist solely by virtue of a federal regulatory scheme...plaintiffs are availing themselves of protections long available under this State's product-liability law...**Plaintiffs' claims run parallel to the FDCA's sameness requirement for labeling warnings, but they are not based on that requirement**." *Reglan,* 226 N.J. at 343 (emphasis added); *see also Laverty*, 197 F. Supp. 3d at 1034 (citing *Bausch v. Stryker Corp*., 630 F.3d 546, 557 (7th Cir. 2010) (rejecting *Buckman* motion where no allegation that defendant made

misrepresentations or omissions to FDA on PMA application)); *Williams v. Smith & Nephew*, 123 F. Supp. 3d 733, 746-747 (D. Maryland, 2015) ("In sum, the only claims impliedly preempted are those that are based on the violation of federal duties that have no freestanding basis in Maryland tort law.").

Here, the claims are traditional state law claims. But nowhere in any Master Complaint do Plaintiffs seek to impose additional obligations on Defendants that conflict with, or pose an obstacle to, compliance with federal requirements. For example, the strict liability manufacturing defect claim is largely based on the introduction of NDMA or other nitrosamines during the manufacture of the valsartan API. The fact that federal regulations also required the drugs to be manufactured to yield the generic equivalent of Diovan or Exforge, without nitrosamine contamination, and that the manufacturer not sell adulterated drugs, is not the basis for the claim. Those are simply parallel federal requirements. "**And this is true even if proving those independent state law claims will rely, in part, on evidence that a federal requirement was violated**." *Williams*, 123 F. Supp. 3d at 747 (emphasis added); *see also Lechler v. 303 Sunset Ave. Condo. Assoc., Inc.*, 452 N.J. Super. 574, 584 (App. Div. 2017); *Carnero v. Deitert*, 10 F. Supp. 2d 440, 444 (D.N.J. 1996) (Lifland, J.); *cf. Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 444 (2005).

A similar analysis applies to the claims premised on defendants' statements and representations, such as the state law express warranty claims. *See Gremo*, 2020 WL 3496917 at *9. This holds true as well for the allegations that the valsartan was misbranded, violated the duty of sameness, and other violations of federal regulations. *See, e.g.*, *In re MDL 2700 Genentech Herceptin (Trastuzumab) Mktg. & Sales Prac. Litig.*, 960 F.3d 1210, 1234, 1240 (10th Cir. 2020) (reversing dismissal of state law claims against drug manufacturer for failing to ensure each vial of drug contained labeled amount of active ingredient, and finding conflict and impossibility

preemption inapplicable); *Lefaivre v. KV Pharm Co.*, 636 F.3d 935, 944 (8th Cir. 2011) (reversing dismissal of consumer state law class action claims against hypertension medication manufacturer for failure to comply with cGMP, and finding preemption inapplicable); *In re Digitek Prods. Liab. Litig.*, MDL No. 2:08-md-01968, 2009 WL 2433468, at *12-13 (S.D. W. Va. Aug. 3, 2009) (finding state law claims against Mylan for manufacture and sale of misbranded or adulterated drugs were not preempted); *Aetna Inc. v. Insys Therapeutics, Inc.*, 324 F. Supp. 3d 541, 555 (E.D. Pa. 2018) (state law claims by TPP for reimbursement of off-label drug use not preempted).

Finally, the same analysis also applies to a state law claim premised on the failure to warn a third party, including the FDA. "State law failure to warn claims – premised on [Restatement] Section 388 – which focus on a manufacturer's failure to report adverse events to the FDA, are not preempted." *Freed v. St. Jude Medical, Inc.*, 364 F. Supp. 3d 343, 359-60 (D. Del. 2019) (citing *Silver v. Medtronic, Inc.*, 236 F. Supp. 3d 889, 899-900 (M.D. Pa. 2016) ("this duty is parallel to FDA reporting requirements.")); *see also McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 837-838 (E.D. Pa. 2016) (applying Section 388 to permit claim based on duty to warn third party, which is "parallel" to FDA reporting requirements). New Jersey courts also apply Section 388. *Arcell v. Ashland Chemical Co., Inc.*, 152 N.J. 471, 495 (Law Div. 1977), *Torsiello v. Whitehall Labs.*, 156 N.J. Super. 311, 320 n.2 (App. Div. 1979), *McGarvey v. G.I. Joe Septic Serv., Inc.*, 293 N.J. Super. 129, 147 (App. Div. 1996).

3. The Primary Jurisdiction Doctrine Is Inapplicable

If Defendants' primary jurisdiction doctrine argument were correct, no pharmaceutical or medical device case would ever proceed in federal court, which certainly is not the case. *See, e.g.*, *Gubaala v. CVS Pharmacy, Inc.*, No. 14-c-9039, 2016 WL 1019794, at *16 (N.D. Ill. Mar. 15, 2016) (refusing to dismiss or stay claims against CVS under primary jurisdiction where CVS was alleged to have sold mislabeled protein powder supplements); *Torres-Hernandez v. CVT Prepaid*

Solutions, Inc., No. 3:08-cv-1057, 2008 WL 5381227 (D.N.J. Dec. 17, 2008) (Wolfson, J.) (rejecting the defendant's argument regarding primary jurisdiction, and holding that "[t]aken to its logical extreme, Defendant's proposed application of the doctrine would permit a pharmaceutical company to avoid negligence claims in federal court by invoking the Food and Drug Administration's authority (putting aside any preemption issues), or force a state court to defer consumer fraud actions against a commercial bank due to Federal Reserve oversight").

Defendants contend that Plaintiffs' breach of implied warranty, strict liability failure to warn, negligence, and manufacturing defect claims should be dismissed based upon the primary jurisdiction doctrine. As an initial and obvious matter, not every case that implicates the potential expertise of federal agencies warrants invocation of primary jurisdiction. Rather, "[f]ederal courts have a 'virtually unflagging obligation . . . to exercise the jurisdiction given them.'" *Raritan Baykeeper v. NL Indus., Inc.*, 660 F.3d 686, 691 (3d Cir. 2011) (quoting *Colo. River Water Conservation Dist. v. United States*, 424 U.S. 800, 817 (1976)). The doctrine is reserved for a "limited set of circumstances" that "requires resolution of an issue of first impression, or of a particularly complicated issue that Congress has committed to a regulatory agency," *Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 760 (9th Cir. 2015), factors not present here.

When determining the applicability of the primary jurisdiction doctrine, courts consider four factors: (1) whether the question "is within the conventional experience of judges" or instead "involves technical or policy considerations within the agency's particular field of expertise"; (2) whether the question "is particularly within the agency's discretion"; (3) whether there exists "a substantial danger of inconsistent rulings"; and (4) whether a "prior application to the agency has been made." *Raritan Baykeeper*, 660 F.3d at 691 (quoting *Global Naps*, 287 F. Supp. 2d at 549). Defendant's liability to Plaintiffs is well within the conventional experience of judges and this Court. Although continued FDA investigation into Defendants' VCDs may occur, the FDA

has already established that Defendants VCDs contained unsafe levels of NDMA and NDEA, resulting in a recall. While 21 U.S.C. §§ 321, 371-72, 375, 393(a) provides that the FDA "has primary jurisdiction to make the initial determination on issues within its statutory mandate," 21 C.F.R. § 10.25(b), that is not the issue here. The FDA has already made the determination that Defendants' VCDs contained unsafe levels of unapproved nitrosamines, and the issues before the Court certainly do not fall within an agency's discretion. *See Raritan Baykeeper*, 660 F.3d at 692 (court retaining jurisdiction, explaining that the plaintiff's "suit **does not amount to a 'collateral attack' on an NJDEP decision**, nor does it seek a remedy that necessarily conflicts with any agency order") (emphasis added); *Bus. Edge Grp., Inc. v. Champion Mortg. Co.*, 519 F.3d 150, 154 (3d Cir. 2008) (holding that it was "more appropriate to remand to the District Court for further proceedings than to transfer it to the agency because **we find that the meaning of the regulation can be determined from its text**") (emphasis added).

4. The Drug Supply Chain Security Act Does Not Preempt Plaintiffs' Claims

Wholesaler and Retail Pharmacy Defendants (but not Manufacturer Defendants) additionally argue that the Drug Supply Chain Security Act ("DSCSA"), 21 U.S.C. § 360eee-360eee-4, preempts all of Plaintiffs' claims against them. *See* Wholesaler Br. at 10-12; Retail Pharmacy Br. at 5-7. DSCSA preemption, however, is very narrow and does not apply here.

The DSCSA narrowly preempts *only* state or local regulations that establish "**requirements for tracing products through the distribution system**," as highlighted below:

> (a)PRODUCT TRACING AND OTHER REQUIREMENTS. Beginning on November 27, 2013, no State or political subdivision of a State may establish or continue in effect any **requirements for tracing products through the distribution system** (including any requirements with respect to statements of distribution history, transaction history, transaction information, or transaction statement of a product as such product changes ownership in the supply chain, or verification, investigation, disposition, notification, or recordkeeping relating to such systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system) **which are inconsistent with, more stringent**

> **than, or in addition to, any requirements** applicable under section 353(e) of this title or this part (or regulations issued thereunder), or which are inconsistent with—
>
> > **(1)** any waiver, exception, or exemption pursuant to section 360eee or 360eee–1 of this title; or
> > **(2)** any restrictions specified in section 360eee–1 of this title.

1 U.S.C. § 360eee-4(a) (emphases added).

Defendants also failed to cite the full relevant language of the statute. Subsection 4(e) expressly states:

> **Nothing in this section shall be construed to preempt State requirements related to the distribution of prescription drugs if such requirements are not related to product tracing** as described in subsection (a) or wholesale distributor and third-party logistics provider licensure as described in subsection (b) applicable under section 353(e) of this title or this part (or regulations issued thereunder).

21 U.S.C. § 360eee-4(e) (emphasis added).

Thus, unless a cause of action under state law seeks to regulate "product tracing" (or licensure requirements, which is not implicated here), by its own terms the DSCSA's preemption clause does not apply. Even if this were not the case, the DSCSA's narrow preemption clause cannot displace all state law; rather, it only incorporates familiar conflict-preemption principles and displaces state law that is "inconsistent with, more stringent than, or in addition to" the DSCSA's requirements.

Thus, the claims against the Wholesaler and Retail Pharmacy Defendants that are not grounded on "product tracing" are not preempted. For example, a breach of warranty claim does not implicate "product tracing." None of the claims hinge on whether these Defendants properly "traced" the products. These are fact-driven questions that do not implicate the DSCSA's narrow preemption clause. In fact, Wholesaler and Retail Pharmacy Defendants also can be found liable for violating state law product tracing requirements that parallel, and therefore do not conflict with, the DSCSA. This, too, is a fact question that cannot be decided at this early juncture.

C. Product Liability Statutes Do Not Subsume Defendants' Liability for Actions Beyond Defective Manufacturing and Design and Failure to Warn.

Defendants' contention that the New Jersey Products Liability Act ("NJPLA") and certain other states' product liability acts "subsume" all of Plaintiffs' common law claims is incorrect. The New Jersey Supreme Court rejected this argument just a few weeks ago. The analysis and principles herein apply equally to any of the other states' product liability acts, including the eight states identified in Defendants' chart.[11]

The New Jersey Supreme Court recently held that "it is the nature of the action giving rise to a claim that determines how a claim is characterized" and "whether the [Product Liability Act ("PLA")] precludes the separate causes of action." *Sun Chem. Corp. v. Fike Corp.*, -- A.3d --, 2020 WL 4342658, at *4, 10 (N.J. 2020). The Court distinguished PLA failure-to-warn claims from those under the Consumer Fraud Act ("CFA") in the following manner:

> The failure to warn of a product defect is likewise cognizable under the PLA, N.J.S.A. 2A:58C-2 (identifying as actionable the failure to provide adequate warnings or instructions for a product), while an affirmative misrepresentation that a specific flaw did not exist or a product had never failed may be brought under the CFA, N.J.S.A. 56:8-2 (identifying as actionable a "misrepresentation or the knowing[] concealment, suppression or omission of any material fact").

Id. at *9. Based on these differences, "the PLA will not bar a CFA claim alleging express or affirmative misrepresentations." *Id.* at *4.

More generally, subsumption only occurs when "the claim is based upon a product's manufacturing, warning, or design defect and therefore covered by the PLA." *Id.* at *10. Claims based on other actions and theories of liability are different and independent from the PLA, and "may be brought in the same action as a PLA claim." *Id.* at *11. Thus, "nothing about the PLA

[11] At best, Defendants' subsumption argument implicates the laws of nine different states.

prohibits a claimant from seeking relief under the CFA for deceptive, fraudulent, misleading, and other unconscionable commercial practices in the sale of the product." *Id.* at 9.

However, the Court did not limit its holding to consumer fraud claims. It wrote that "the [PLA] and common law tort actions do not apply to damage caused to the product itself, or to consequential but purely economic losses caused to the consumer because of a defective product." *Id.* at 5, n.2 (quoting *Ford Motor Credit Co., LLC v. Mendola*, 48 A.3d 366, 374 (N.J. App. Div. 2012)). These economic damages are recoverable under contract theories, which are independent and viable either alongside a PLA claim or without one. *Id.* (citing *Dean v. Barrett Homes, Inc.*, 8 A.3d 766 (N.J. 2010)). As the Court clarified, "it is the theory of liability underlying the claim that determines the recoverable damages." *Id.* at *10.

For example, the PLA explicitly excludes "actions for harm caused by breach of an express warranty." *Id.* at *7. Therefore, Plaintiffs' express warranty claims are not subsumed, and Plaintiffs are entitled to "the difference at the time and place of acceptance between the value of the goods accepted and the value they would have had if they had been as warranted" as well as "incidental and consequential damages." N.J.S.A. 12A:2-714.

Defendants rely on *Sinclair v. Merck & Co.*, 948 A.2d 587, 772 (N.J. 2008), *In re Lead Paint Litigation*, 924 A.2d 484 (N.J. 2007), and their progeny. However, *Sun Chemical* distinguished those cases as idiosyncratic decisions based on the plaintiffs' failure to plead claims beyond defective manufacturing and design and failure to warn. *Sun Chemical*, 2020 WL 4342658, at *8. "[I]n *Sinclair* the CFA and PLA causes of action were brought in separate but nearly indistinguishable counts," and "the relief the plaintiffs sought under the CFA count of the complaint matched the PLA count word-for-word." *Id.* In *Lead Paint*, "[t]he central focus of plaintiffs' complaints is that defendants were aware of dangers associated with lead -- and by extension, with the dangers of including it in paint intended to be used in homes and businesses --

and failed to warn of those dangers." *Id.* Defendants' remaining cases fail to address how the inadequate pleadings dictated the holdings of *Sinclair* and *Lead Paint*. Plaintiffs have attached a chart discussing the law of states with similar subsumption rules. *See* Plaintiffs' Appendix of State Law Authority ("Pls.' Appx.").

The ELMC is an "economic damages action." As already explained, the PLA does not subsume actions for damage to a product or for purely economic damages that result from a defective product. *Sun Chemical*, 2020 WL 4342658, at 5, n.2. And the ELMC only requests economic damages. *See* ELMC, Prayer for Relief ¶ E. Moreover, the ELMC states that "[e]ach Defendant made and breached express and implied warranties and also made affirmative misrepresentations and omissions to consumers about their adulterated and/or misbranded VCDs," and then provides over fifty examples of such affirmative representations and material omissions. *See, e.g.*, ELMC ¶¶ 360-413. The PLA does not subsume Defendants' liability for these types of actions, and neither do similar statutes in other states. *Sun Chemical*, 2020 WL 4342658, at *4; *see also* Pls.' Appx.

The MMMC seeks "injunctive and *monetary* relief, including creation of a fund to finance independent medical monitoring services." *Id.* (emphasis added). In New Jersey, medical monitoring is a remedy, not a cause of action. *See Sinclair*, 948 A.2d at 589. Plaintiffs' allegations of "cellular damage" and "genetic harm" requiring medical treatment establish the physical injury required under the PLA. *See Caterinicchio v. Pittsburgh Corning Corp.*, 605 A.2d 1092, 1096 (N.J. 1992) (holding that whether an injury is sufficiently physical "is factual and remains within the province of the trier of fact").

The motion to dismiss Plaintiffs' claims on the basis of subsumption should be denied.

D. The Complaints Adequately Plead All State Law Claims

1. Piecemeal Dismissal Is Inappropriate

Defendants' motions seek dismissal of claims in the various master complaints based on law in some, but not all, states where VCDs were prescribed. For example, Defendants seek to dismiss only parts of the express warranty Count for eleven states' laws, leaving the Count otherwise intact as to the remaining states (as set forth below, Defendants' characterizations of those eleven states' laws regarding express warranty claims are inaccurate, highlighting why the Court should strike these voluminous charts that contain virtually no argument).

However, for both legal and practical reasons, this sort of piecemeal approach to dismiss claims is not appropriate at this early Rule 12(b)(6) stage. Rather, these state-by-state issues should be addressed at summary judgment, where a more robust and individualized factual record will better allow the parties to adequately brief these issues for the Court.

Rule 12(b)(6) does not allow a party to seek partial dismissal of a claim. *See, e.g.*, *BBL, Inc. v. City of Angola*, 809 F.3d 317, 325 (7th Cir. 2015); *Redwind v. W. Union, LLC*, No. 3:18-CV-02094-SB, 2019 WL 3069864, at *3-4 (D. Or. June 21, 2019), *report and recommendation adopted*, No. 3:18-CV-2094-SB, 2019 WL 3069841 (D. Or. July 12, 2019). As stated by the Seventh Circuit:

> A motion to dismiss under Rule 12(b)(6) doesn't permit piecemeal dismissals of parts of claims; the question at this stage is simply whether the complaint includes factual allegations that state a plausible claim for relief.
>
> Summary judgment is different. The Federal Rules of Civil Procedure explicitly allow for "[p]artial [s]ummary [j]udgment" and require parties to "identif[y] each claim or defense—or the part of each claim or defense—on which summary judgment is sought." At the summary-judgment stage, the court can properly narrow the individual factual issues for trial by identifying the material disputes of fact that continue to exist.

City of Angola, 809 F.3d at 325.

When two theories based on the same facts—and part of a single claim for relief—are presented in a complaint, and a defendant only challenges the sufficiency of the complaint as to one of the theories, the claim cannot be dismissed. And, the challenged theory cannot be dismissed either, because dismissal of theories (as opposed to claims) is inappropriate at the motion to dismiss stage. *Winstead v. Lafayette Cty. Bd. of Cty. Commissioners*, 197 F. Supp. 3d 1334, 1341 (N.D. Fla. 2016). That rule applied here prevents the piecemeal dismissal of causes of action from the master complaints when the claims would survive under at least one state's laws.

Additionally, matters unique to each personal injury case, such as prescription history, medical conditions, etc., would need to be addressed by the Court. However, the only pleadings currently before the Court on Defendants' motions are the Master Complaints, which by the nature do not include each allegation necessary to analyze those legal issues. *See In re FEMA Trailer Formaldehyde Prods. Liab. Lit.*, No. 07-1873, 2012 WL 1580761, at * 2 (E.D. La. May 4, 2012) ("the record is devoid of the facts necessary to decide the multiple questions inherent" as to each personal injury plaintiff).

Finally, practical considerations also favor resolving issues that vary depending on the particular facts and state law applied. For instance, the parties are unable to adequately brief the law of all fifty states given the page and time constraints associated with a single brief. State-specific issues can and should be addressed in individual personal injury cases at the appropriate juncture, and at class certification for the economic loss and medical monitoring actions.

2. The Master Complaints Adequately Plead Express Warranty, Implied Warranty, and Magnuson-Moss Warranty Claims

Each of the Master Complaints validly states causes of action for breach of express and implied warranties pursuant to the numerous state laws pleaded, as well as violations of the

Magnuson-Moss Warranty Act.[12] To bolster their losing dismissal arguments, Defendants have presented a hodgepodge of inapposite case law, selective readings of the allegations of the Master Complaints, and finger-pointing to the other categories of Defendants.

a. Plaintiffs are not required to address state law claims not raised by Defendants in their Motions to Dismiss

Defendants make sweeping statements about the viability of Plaintiffs' warranty claims in their briefs, but only actually list a small number of states in their charts where they claim Plaintiffs' warranty claims are precluded. In essence, Defendants endeavor in their briefs to engage in "for example"-type arguments hoping that this Court will apply such arguments more broadly than the specific examples given. There is no obligation for a plaintiff to affirmatively address non-raised arguments or aspects of claims where there is no specific dismissal argument made (e.g., specific states not raised by Defendants).[13]

b. The Master Complaints adequately allege injury for breach of warranty claims

The Manufacturer Defendants cite a string of inapposite cases to make an argument that the Master Economic Loss and Medical Monitoring Complaints insufficiently allege injury or so-called "loss of functionality." Mfr. Br. at 46-47.

The Economic Loss Master Complaint alleges that Plaintiffs and Class Members paid out of pocket for the adulterated VCDs. *See, e.g.*, ELMC ¶¶ 422-424. The Economic Loss Master Complaint also alleges that the VCDs purchased by Plaintiffs and Class Members were

[12] Because the viability of the Magnuson-Moss claims depends on applicable state law, and because the state warranty claims are viable for the reasons discussed in this section, so too, are the Magnuson-Moss claims.

[13] Additionally, as discussed *supra* at fn. 1, all legal argument Defendants make in their additional appended "charts" should be stricken from the record. Defendants had 120 pages of briefing with which to make such arguments, but chose not to do so, and instead improperly appended 112 pages of legal argument to their brief, doubling their page limitation.

"worthless" (*id.* ¶¶ 4, 359, 371) and "have no market value" (*id.* ¶¶ 445, 454 (express warranty causes of action)) because, among other things, they were "illegally manufactured, sold, labeled, marketed, and distributed in the United States" (*id.* ¶¶ 4, 7, 10, 173, 359, 370) to Plaintiffs and Class Members.

In a November 2019 published opinion, the Eleventh Circuit Court of Appeals agrees that this **exact** type of injury is cognizable. *Debernardis v. IQ Formulations, Incorporated* 942 F.3d at 1084-85 (11th Cir. 2019). In *Debernardis*, the Eleventh Circuit discussed the "benefit-of-the-bargain" theory of economic damages and wrote the following:

> Ordinarily, when a plaintiff purchases a product with a defect, the product retains some value, meaning her benefit-of-the-bargain damages are less than the entire purchase price of the product. But "[a] notable exception" to this general rule applies when the "product is rendered valueless as a result of a defect." When a plaintiff receives a worthless product, his benefit of the bargain damages will be equal to the entire purchase price of the product. The benefit-of-the-bargain theory thus recognizes that a purchaser who acquires a product with significant defects may effectively receive nothing of value.
> …
> Beginning with the first question, **we accept, at least at the motion to dismiss stage, that a dietary supplement that is deemed adulterated and cannot lawfully be sold has no value.** Through the FDCA, as amended by the DSHEA, Congress banned the sale of adulterated dietary supplements because of its concern that such substances could not safely be ingested. See 21 U.S.C. §§ 331(a), 342(f)(1)(B), 393(b)(2). A person who purchased an adulterated dietary supplement thus received a product that Congress judged insufficiently safe for human ingestion. **Given Congress's judgment, we conclude that the purchaser of such a supplement received a defective product that had no value. This conclusion is consistent with the well-established benefit-of-the-bargain theory of contract damages**, which recognizes that some defects so fundamentally affect the intended use of a product as to render it valueless.

Debernardis, 942 F.3d at 1084-85 (emphases added).

Accordingly, the Eleventh Circuit "conclude[d] that the plaintiffs plausibly alleged that they suffered an economic loss when they purchased supplements that were worthless because the FDCA prohibited sale of the supplements." *Id.* at 1080.

The analysis is no different when it comes to adulterated pharmaceuticals. Plaintiffs and Class Members here allege they received products, namely the VCDs, that Congress judged insufficiently safe for human ingestion. Accordingly, the VCDs for which Plaintiffs and Class Members paid out of pocket money were "valueless" because of these defects that were so significant that it rendered the VCDs adulterated and illegal to commercialize in any way in the United States. *See* 21 U.S.C. 351(a)(1) & (a)(2)(B). The adulterated nature of the VCDs received by Plaintiffs and Class Members is detailed at length in the Master Complaints.

The cases cited by Defendants are entirely off point. In *Hoffman,* the *pro se* plaintiff (who did not file an opposition to the motion to dismiss) merely alleged that the supplement he received contained a small amount of lead, and did not even allege that the presence of the lead rendered the supplement adulterated. *Hoffman v. Nutraceutical Corp.*, No. 12-5803, 2013 WL 2650611, at *4 (D.N.J. June 10, 2013) (Salas, J.).

Likewise, in *Hammer v. Vital Pharmaceuticals, Inc.* No. 11-4124, 2012 WL 1018842, at *6 (D.N.J. Mar. 26, 2012) (Wolfson, J.), the theory of liability was based not on an adulteration of the product, but rather the use of non-natural ingredients without disclosure.

In *Bowman v. RAM Medical, Inc.*, the plaintiff simply alleged that the product was "counterfeit" with nothing more. No. 10-cv-403, 2012 WL 1964452 (D.N.J. May 31, 2012) (Cavanaugh, J.) ("Plaintiffs do not supply any supporting facts . . . rendering the product valueless or unfit."). Although Plaintiffs maintain *Bowman* was wrongly decided, the case is distinguishable because the Master Complaints here allege in detail the rampant cGMP violations and contamination of Defendants' VCDs that rendered the products adulterated and illegal to sell.

Finally, *Crozier*, a false advertising case, involving the marketing of a Neosporin®-branded antiseptic spray that did not contain antibiotics (the claim being that using the Neosporin brand name was misleading because consumers associate Neosporin with antibiotics) clearly has no application to this set of facts. *Crozier v. Johnson & Johnson Consumer Cos., Inc.*, 901 F. Supp. 2d 494 (D.N.J. 2012) (Simandle, J.).

c. Breach of warranty claims are viable against Retail Pharmacy Defendants who dispense adulterated drugs, and Wholesaler Defendants

Even though Retail Pharmacy Defendants profit billions per year from selling prescription medications to consumers (*see, e.g.* ELMC ¶¶ 85, 93, 98) and – in the case of generic medicines such as the VCDs – actually select the medication to dispense (*id.* ¶ 82) in nearly all instances, they argue that they are not merchants or sellers for purposes of warranty claims.

The Retail Pharmacy Defendants cite a smattering of cases, but fail to acknowledge a critical issue-dispositive distinction: this case does not involve retailers dispensing a properly-manufactured drug that was later determined to produce harmful side effects but rather one that was contaminated, non-cGMP compliant, and thus adulterated such as the VCDs at issue here. In *Fagan v. AmerisourceBergen Corporation*, the Court found this distinction dispositive in allowing the warranty claims to proceed against retail pharmacies. 356 F. Supp. 2d 198, 215-16 (E.D.N.Y. 2004) (finding a distinction between the pharmacy "filling a prescription of an adulterated drug" and dispensing "a drug that was later determined to produce harmful side effects" and noting that "[o]ther cases that have dismissed warranty claims also failed to contain evidence that the product was adulterated, misbranded, or otherwise defective … and, thus, are distinguishable from the present case" (collecting cases)).

All of the cases cited by the Retail Pharmacy Defendants involve allegations of defectively designed drugs, not adulterated drugs at issue here. The *Yasmin and Yaz* and *Rezulin* MDL

litigations involved allegations of defectively designed oral contraceptives and diabetes medications, respectively. Rezulin was eventually withdrawn from the market due to its inherent design defects. *See also Murphy v. E.R. Squibb & Sons, Inc.*, 710 P. 2d 247 (Cal. 1985) ("The complaint sought damages on the theory of strict liability, alleging that the drug was defectively designed …."); *Carrozza v. CVS Pharmacy, Inc.*, 391 F. Supp. 3d 136, 140 (D. Mass. 2019) (plaintiff's claim was based on having an allergic reaction to ingestion of antibiotic Levaquin, not that it was adulterated); *Presto v. Sandoz Pharm. Corp.*, 226 Ga. App. 547, 547, 487 S.E.2d 70, 72 (1997) (plaintiffs' claim was "that defendants are tortiously liable for the suicide of [plaintiffs' son], for failing to warn him of the dangers of discontinuing the use of the drug Clozaril"). This distinction cannot be ignored – while retail pharmacies (and wholesalers) had no choice but to purchase and stock the defectively designed branded drugs at issue in the aforementioned design defect cases, here, in this case, Retail Pharmacy and Wholesalers Defendants had a wealth of options from whom they could purchase generic valsartan, and affirmatively chose to purchase VCDs from Manufacturer Defendants.

The breach of warranty claims against Retail Pharmacy Defendants are viable based on Plaintiffs' allegations in the Master Complaints that Retail Pharmacy Defendants dispensed adulterated VCDs, and based on Retail Pharmacy Defendants' own admission that warranty claims sound in strict liability.

Warranty claims are also viable against Wholesaler Defendants based on indemnification agreements alleged to exist, as well as on agency principles of liability. *See, e.g.*, *Geraczynski v. Nat'l R.R. Passenger Corp.*, No. 11-6385, 2015 WL 4623466 (D.N.J. July 31, 2015) (Chesler, J.) ("Indemnity is required not only as a matter of contract but also as a matter of common law, which requires a product distributor to indemnify other distributors and sellers further down the chain of distribution, with the ultimate responsibility for losses caused by product defect resting at the top

of the chain with the manufacturer."). This is a fact question not amenable to dismissal on a Rule 12 motion. Moreover, by asserting that the Manufacturer Defendants are the proper parties to shoulder the liability (and, implicitly the damages) here, *see* Wholesaler Br. at 6, Wholesaler Defendants have put at issue the indemnification arrangements between them, as well as the financial ability of Manufacturer Defendants to satisfy any judgment. Both of these issues need to be explored in discovery; they cannot be given short-shrift based on nothing more than Wholesaler Defendants' say-so at the Rule 12 stage.

d. The Master Complaints adequately plead common law breach of express warranties as to all 50 states and territories

The Manufacturer Defendants argue that there is no privity between consumers and them, and that the Master Economic Loss and Medical Monitoring Complaints fail to adequately plead these elements. Defendants trot out a handful of cases to support this theory, and ignore the notable exceptions to the requirement of privity (or that the law may supply privity in certain contexts) in the context of express warranty claims that may be applicable.

First, Defendants' lack of privity arguments are limited to Plaintiffs' express warranty claims in eleven (11) states.[14] *See* ECF 520-5, at 40-41. This is because the vast majority of states simply do not require privity of contract for express warranty claims, or the law supplies such privity under circumstances applicable to this case which are adequately alleged in the Master Economic and Medical Monitoring Complaints. The majority of states, such as New Jersey, have eliminated any requirement of privity in the context of express warranty claims. *See, e.g.*, *Dzielak v. Whirlpool Corp.*, 26 F. Supp. 3d 304, 322 (D.N.J. 2014). Other states have broad privity exceptions or will supply privity as a matter of law. For example, California law provides privity

[14] Those states include: Connecticut, Florida, Georgia, Illinois, Indiana, Iowa, Kentucky, Maryland, Nevada, Virginia, and Wisconsin.

in the express warranty context "where representations are made by means of labels or advertisements." *In re Nexus 6P Products Liability Litigation*, 293 F. Supp. 3d 888, 941 (N.D. Cal. 2018) (citing *Burr v. Sherwin Williams Co.*, 268 P.2d 1041, 1048 (Cal. 1954)).

Even among the eleven (11) states where Defendants argue for dismissal, ***literally all*** contain exceptions to privity for express warranty claims implicated by the allegations in the Master Complaints highlighting the danger of allowing Defendants to argue for dismissal merely by listing a state in a chart with no explanation other than a single cite as to its inclusion. For example:

- **Connecticut** courts addressing express warranty claims have supplied privity where no other remedies are available. *Utica Mut. Ins. Co. v. Denwat Corp.*, 778 F. Supp. 592, 595-596 (D. Conn. 1991) (citing cases).

- **Florida** courts have supplied privity for express warranty claims where the defendant has voluntarily provided a warranty that runs in favor of remote purchasers of its product. *See Aprigliano v. Am. Honda Motor Co., Inc.*, 979 F. Supp. 2d 1331, 1340 (S.D. Fla. 2013) (citing cases).

- **Georgia** courts have stated that "it is possible for the ultimate consumer to establish privity of contract if the manufacturer extends an express warranty to her." *Lee v. Mylan Inc.*, 806 F. Supp. 2d 1320, 1327-28 (M.D. Ga. 2011) (finding express warranty privity under Georgia law in ultimate consumer claim against Mylan).

- **Illinois** courts have recognized an exception to the privity requirement, holding that "manufacturer documents given directly to the buyer prior to a purchase may give rise to an express warranty." *Wheeler v. Sunbelt Tool Co.*, 537 N.E.2d 133, 1341 (Ill. 1989).

- The **Indiana** Court of Appeals has recognized an exception to the privity requirement for breach of express warranty claims against a manufacturer that are based on representations in advertisements and/or on a product label. *Prairie Prod., Inc. v. Agchem Division-Pennwalt Corp.*, 514 N.E. 2d 1299 (Ind. App. 1987); *see also In re ConAgra Foods, Inc.*, 90 F. Supp. 3d 919, 1002-03 (C.D. Cal. 2015) (discussing Indiana law regarding express warranty claims and privity).

- The **Iowa** Supreme Court recently held that "[i]f a defective product results only in economic loss, we only allow the buyer to bring a claim under an express warranty for direct economic losses against a remote seller and warranty claims for consequential economic losses against the seller in privity with them unless disclaimed. *Des Moines Flying Serv., Inc. v. Aerial Servs. Inc.*, 880 N.W.2d 212, 222 (Iowa 2016).

- **Kentucky** courts have recognized an exception to privity where "the manufacturer made valid express warranties for the benefit of consumers." *Estate of DeMoss by & through DeMoss v. Eli Lilly & Co.*, 234 F. Supp. 3d 873, 884 (W.D. Ky. 2017). Even though the *DeMoss* case was in the context of Kentucky Consumer Protection Act, these courts would likely apply the same analysis to common law express warranty claims.

- **Maryland** courts have recognized exceptions to privity in the express warranty context based on third-party beneficiary status, equitable estoppel, assignment, agency relationships, or successors in interest. *Pulte Home Corp. v. Parex, Inc.*, 923 A.2d 971 (Md. App. 2007).

- **Nevada**'s Supreme Court has held "that lack of privity between the buyer and manufacturer does not preclude an action against the manufacturer for the recovery of economic losses caused by breach of warranties."[15] *Hiles Co. v. Johnston Pump Co. of Pasadena, Cal.*, 93 Nev. 73, 560 P.2d 154 (Nev. 1977).

- Under **Virginia** law, a "[l]ack of privity between plaintiff and defendant shall be no defense in any action brought against the manufacturer or seller of goods to recover damages for breach of warranty, express or implied, or for negligence, although the plaintiff did not purchase the goods from the defendant, if the plaintiff was a person whom the manufacturer or seller might reasonably have expected to use, consume, or be affected by the goods[.]" section VA Code Ann. 8.2-318; *see also Beard Plumbing and Heating, Inc. v. Thompson Plastics, Inc.*, 254 Va.240, 491 S.E.2d 731 (Va. 1997).

- **Wisconsin** law does not require the ultimate purchaser to deal directly with the manufacturer of a product in order to sue the manufacturer for breach of the manufacturer's express warranty. *Lamont v. Winnebago Indus., Inc.*, 569 F. Supp. 2d 806, 815 (E.D. Wis. 2008) (citing *Sunnyslope Grading, Inc. v. Miller, Bradford and Risberg, Inc.*, 148 Wis.2d 910, 437 N.W.2d 213 (Wis. 1989)).

The Master Economic Loss Complaint alleges that express warranties were given directly from the Manufacturer Defendants to consumers of VCDs. *See* ELMC ¶¶ 360-406. For example, each VCD prescription dispensed to patients contained manufacturer warranties within the product labeling including but not limited to simply calling the product FDA-approved "valsartan" when that was not the case. Furthermore, each VCD prescription was dispensed with a patient information leaflet (variously known as a medication guide) authored by the Manufacturer

[15] The Nevada case cited by the Manufacturer Defendants is an unpublished table opinion. The only statement that case makes regarding privity and warranties is in the implied warranty context. ECF 520-5.

Defendants and *addressed specifically to the patient* that makes express warranties regarding the VCDs, including regarding the active and inactive ingredients. *Id.* Finally, Plaintiffs have alleged and can support a theory of express warranty liability based on consumers being third-party beneficiaries of manufacturer express warranties.[16]

The existence of these and other warranties are subject to discovery, and that discovery may implicate, where applicable, certain exceptions to privity requirements under state express warranty laws. Accordingly, it is premature for the Court to dismiss any state express warranty claim where discovery may yield evidence of a warranty that would trigger any particular state law exception to privity in this context.

e. The Master Complaints allege the existence of manufacturer express warranties that formed a "basis of the bargain"

Manufacturer Defendants argue that Master Complaints do not allege that any of the alleged express warranties formed the basis for the bargain, which Defendants contend is a requirement in certain states listed in their charts. *See* ECF 520-5 at 42-44. However, it is unnecessary for the Court to engage a multi-state survey here, because Plaintiffs do in fact allege certain express warranties formed a basis of the bargain for each and every single purchase of VCDs.

As set forth above, Manufacturer Defendants provided express warranties in the product labeling, including labeling their products by their generic active ingredient names (e.g., valsartan or valsartan HCT), in the patient information leaflets, on a third-party beneficiary basis, and elsewhere. Those express warranties formed a basis of the bargain for the ultimate consumers of

[16] Discovery has already revealed the existence of express warranties made by manufacturers to wholesalers/retailers, which contain express warranties made for the benefit of consumers as intended third party beneficiaries.

VCDs. The Master Economic Loss Complaint repeatedly alleges that Plaintiffs and Class Members would not have, and could not have, purchased the VCDs but for the express warranties provided by the Manufacturer Defendants in their labeling materials, simply by calling the product valsartan, and through patient information leaflets dispensed with each prescription. *See, e.g.*, ELMC ¶¶ 11-34. Those allegations are emphasized specifically in the express warranty cause of action for consumer Plaintiffs and Class Members. *Id.* ¶ 444. Those allegations are plausible because Plaintiffs and Class Members could not have purchased the VCDs but for the express warranties made by Manufacturing Defendants in their labeling, by referring to the products as valsartan, and through their patient information leaflet materials. Furthermore, Plaintiffs and Class Members would not have purchased an entirely different drug from what they were prescribed (especially one that contained carcinogenic active ingredients). To the extent express warranty claims require a basis-for-the-bargain showing, the Master Economic Loss Complaint contains sufficient allegations to plead that element adequately and plausibly.

Even so, Defendants' characterization of this "element" of some states' express warranty claims is deliberately misleading. Defendants simply cite UCC statutes without offering case law to interpret what is actually required by those states' courts. *See* ECF 520-5, at 42-44. Indeed, the case law of most states makes clear reliance/basis of the bargain is not an element of the express warranty claim. *See, e.g.*, *In re Gen. Motors Corp. Dex-Cool Prods. Liab. Litig.*, 241 F.R.D. 319-20 (S.D. Ill. 2007) ("It appears that a large number of states in the proposed class, possibly a majority, hold that reliance is not an element of an express warranty claim.") (collecting cases from South Dakota, Florida, Connecticut, Kansas, Alabama, Hawaii, the District of Columbia, New York, Ohio, and Virginia as examples)); *see also Lutz Farms v. Asgrow Seed Co.*, 948 F.2d 638, 645 (10th Cir. 1991) ("It appears that the majority of jurisdictions which have addressed the issue have found it unnecessary to require reliance from the buyer before a statement by the seller

can be considered an express warranty."); *Barden v. Hurd Millwork Co., Inc.*, 249 F.R.D. 316, 321-22 (E.D. Wis. 2008) (finding reliance/basis for the bargain not required in, at minimum,[17] Connecticut, Georgia, Indiana, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Missouri, Nebraska, New Jersey, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, Vermont, Virginia, West Virginia, Wisconsin, and the District of Columbia). The *General Motors* court also compiled a selection of states where a rebuttable presumption of reliance is created. *Id.* at 320-21 (collecting cases from Illinois, Pennsylvania, Wyoming).

As such, it is not necessary to rebut Manufacturer Defendants' improperly-appended half-baked charts for each and every state when full analysis is lacking. Defendants have not met their burden in presenting such a dismissal argument, and indeed the Court should strike Defendants' charts for this very reason.

f. The Master Complaints sufficiently identify the express warranties

The Master Complaints more than sufficiently identify the source of the express warranties made by the Manufacturing Defendants. Based on the Manufacturing Defendants' Chart, it appears that the Manufacturing Defendants demand that the specific express warranties be identified each time they are mentioned in the Master Complaints. Neither notice pleading, nor common sense, require such specificity each and every time express warranties are alleged.

The Master Complaints more than adequately identify the express warranties based on the labeling, the product name, the patient information leaflets/medication guides, as well as express

[17] The list provided by the court also included another limiting factor of pre-suit notice. The actual list of states that do not require reliance is much more comprehensive.

warranties detailed elsewhere in the Economic Loss Master Complaint and the other Master Complaints.[18]

g. Defendants are liable for representations/warranties made concerning the safety and efficacy their VCDs, not VCDs generally

Plaintiffs do not rely on general representations that the VCDs are "safe and effective" as the source of any warranty. *See* ECF 520-3, at 49. To be clear, Plaintiffs do not allege that properly-manufactured Diovan, Diovan HCT, Exforge, or Exforge HCT (or their generic equivalents) are not safe and effective for the indications approved by the FDA when they are not "adulterated" as that term is used in 21 U.S.C. § 351. Nor do Plaintiffs allege or state a cause of action that Manufacturer Defendants should have provided some kind of warning or disclosure in their FDA-approved labeling materials that was not already contained therein.

Rather, Plaintiffs allege that the FDA-approved labeling materials contain express warranties that the Manufacturing Defendants failed to meet with their VCDs (e.g., warranties regarding the sameness of their products to the respective reference listed drugs (RLDs), warranties that the VCDs supplied to and reimbursed by Plaintiffs and Class Members meet the specifications of Defendants' ANDAs, or warranties listing the active ingredients of the VCDs).

Defendants' citation to the *Avandia* litigation is unavailing. In that case, the brand drug was manufactured as intended by the manufacturer and as approved by the FDA, but it allegedly contained design defects that caused excess cardiovascular adverse events in an already vulnerable diabetic population. Inversely here, there is no allegation that properly-manufactured valsartan is not safe and effective; the case involves Defendants' adulterated (and thus entirely new,

[18] Alternatively, since this is a notice issue raised by Manufacturing Defendants, Plaintiffs should be allowed to amend to state with specificity the express warranties on which they rely should the Court deem notice insufficient.

unapproved drugs) marketed as approved generic versions of Diovan and Exforge (and HCT products).

h. The Master Complaints adequately plead breach of implied warranty in all 50 states and territories

Defendants mostly assert legal challenges regarding privity, pre-suit notice, and a lack of injury for Plaintiffs' implied warranty claims. Defendants' lack of injury argument is addressed *supra*.

All states and territories listed in the Master Complaints recognize implied warranty claims for merchantability and fitness.[19] Manufacturer Defendants' VCDs have been alleged to be non-merchantable and unfit in the most obvious sense of the terms; it was unlawful for Defendants to place the VCDs at issue herein into the stream of commerce (*i.e.*, distribute, sell, dispense in the United States) because Congress has determined that adulterated pharmaceuticals are non-merchantable and unfit for any use. *See* 21 U.S.C. § 351; *see also Debernardis*, 942 F.3d at 1085-86.

i. Retail Pharmacy Defendants' implied warranties

Implied warranties are most clearly established between consumers/purchasers (including TPPs) of the VCDs and Retailer Pharmacy Defendants. There is a direct buyer-seller relationship between consumers who purchase (and TPPs who pay a portion of the purchase price) and retailers who sell them the drug. Direct privity exists in such transactions, as well as the implied warranties that such transactions carry.

As conceded by Retail Pharmacy Defendants in their own brief, such claims do not depend on a showing of fault. *See* Retail Pharmacy Br. at 15 ("[W]arranty liability typically attaches

[19] Under Louisiana's Civil Code this claim is referred to as a redhibition claim. *See* La. Civ. Code art. 2520.

without regard to fault."). The idea behind no-fault implied warranty combined with traditional requirements of privity for such claims was to force each buyer to pursue their remedies directly upstream until the ultimate wrongdoer is reached.[20]

It is the lack of fault for implied warranty liability to attach that has led the Retail Pharmacy Defendants to negotiate indemnity agreements and express warranties for the benefit of consumers with the Manufacturer Defendants, whereby the Manufacturers have agreed to indemnify the Retail Pharmacies for any liability related to the dispensing of said Manufacturer's drugs, and to make express warranties for the benefit of the ultimate consumers of their drugs. Those agreements exist between all of the Retailer Pharmacy Defendants and Manufacturers or Wholesalers in this case.[21] *See, e.g.*, ELMC ¶ 409.

The error that underlies Retail Pharmacy Defendants' warranty liability arguments is demonstrated by the unjust outcome that would occur if Manufacturer Defendants indeed are exempt from liability under any particular state's laws simply based on a supposed lack of privity. The law would in effect be barring an implied warranty claim altogether if a consumer cannot sue the wrongdoer directly (i.e., the manufacturers), but also cannot sue the seller with whom they are in privity (i.e., the retailers). Such an outcome would essentially immunize the entire pharmaceutical supply chain from economic damages liability.

[20] For the sake of efficiency, many states have since abrogated a need for privity so that the ultimate consumer may sue the wrongdoer directly for economic damages under an implied warranty theory of relief.

[21] Some of these indemnification agreements have already been produced in discovery, and many of them have been improperly redacted.

j. Manufacturer and Wholesaler Defendants' implied warranties

Manufacturer and Wholesaler Defendants argue lack of privity and pre-suit notice for a handful of states. They are either wrong as to the law of those states, or it is too early for the Court to make such a decision.

The Manufacturer Defendants fail to acknowledge that many states (nearly all cited in their implied warranty chart, *see* ECF 520-5, at 35-37) will find privity for purposes of implied warranty claims under a number of circumstances applicable factually to this case including but not limited to: (1) the manufacturer has made express warranties to the ultimate consumer (Florida[22], Georgia[23], Illinois[24], Vermont[25]); (2) or under a third party beneficiary theory where the

[22] *Ohio State Troopers Ass'n v. Point Blank Enter., Inc.*, No. 0:17cv62051, 2018 WL 3109632, at *6 (S.D. Fla. April 5, 2018) ("Florida courts have found the privity requirement to be satisfied when a manufacturer directly provides a warranty to, or otherwise has direct contact with, a buyer who purchases from a third party." (citing *Global Quest, LLC v. Horizon Yachts, Inc.*, 849 F.3d 1022, 1032 (11th Cir. 2017) and *Cedars of Lebanon Hosp. Corp. v. European X-Ray Dist. of Am.*, 444 So. 2d 1068, 1072 n.4 (Fla. Dist. Ct. App. 1984)).

[23] *Lee v. Mylan Inc.*, 806 F. Supp. 2d 1320, 1327–28 (M.D. Ga. 2011) ("Because privity is established by the alleged express warranty to the Plaintiff's mother, the Plaintiff also may bring claims for the implied warranties of merchantability and fitness for a particular purpose.").

[24] *See In re McDonald's French Fries Litig.*, 503 F.Supp.2d 953, 957 (N.D.Ill.2007) (stating that Illinois state law recognizes a privity exception where the "manufacturer 'expressly warranted its goods to the ultimate consumers and this was the basis for the bargain and relied upon by plaintiffs"); *Canadian Pac. Ry. Co. v. Williams-Hayward Protective Coatings, Inc.*, No. 02cv88, 2005 WL 782698, at *15 (N.D. Ill. Apr. 6, 2005) ("In the context of a buyer purchasing a product from a dealer and not the manufacturer, Illinois courts have concluded that brochures, documents, and advertisements may be the basis of express warranty.").

[25] *Moffitt v. Icynene, Inc.*, 407 F. Supp. 2d 591, 598 (D. Vt. 2005) ("[T]he Vermont Supreme Court has dispensed with privity when personal injury, property damage, or an express warranty made directly from the defendant to the plaintiff is present.").

manufacturer has made express warranties to a dealer or intermediate seller (Alabama[26], Florida[27], Nevada[28], North Carolina[29], Ohio[30], Utah[31], Washington[32]); (3) where the product is meant to be

[26] *Harris Moran Seed Co. v. Phillips*, 949 So. 2d 916, 923 (Ala. Civ. App. 2006) (stating that under Alabama law "a vertical nonprivity purchaser who has suffered only economic loss can recover from a remote seller or manufacturer under a theory that the purchaser is a third-party beneficiary of a contract containing the manufacturer's express warranty to a dealer or an intermediate seller") (citing *Bay Lines, Inc. v. Stoughton Trailers, Inc.*, 838 So.2d 1013 (Ala.2002))).

[27] *See Ohio State Troopers Ass'n, Inc.*, 2018 WL 3109632, at *7 (citing *Pegasus Aviation IV, Inc. v. Aircraft Composite Technologies, Inc.*, No. 1:16-cv-21255-UU, 2016 WL 3390122, *5 (S.D. Fla. June 17, 2016) ("Plaintiff can state a claim for breach of express warranty and breach of implied warranty of merchantability, even without direct privity, as long Plaintiff adequately alleges that it was a third party beneficiary of the contract for the sale of the thrust reversers.") and *Sanchez-Knutson v. Ford Motor Co.*, 52 F. Supp. 3d 1223, 1233-34 (S.D. Fla. 2014) ("Plaintiff can pursue a claim of breach of implied warranty through third-party beneficiary law.")); *see also Toca v. Tutco, LLC*, 430 F. Supp. 3d 1313, 1326 (S.D. Fla. 2020).

[28] *Soltani v. GP Indus.*, 373 P.3d 962 (Nev. 2011) (Nevada's Supreme Court intimating that an end consumer may be able to pursue implied warranty claims for economic losses against a manufacturer on a third-party beneficiary theory).

[29] *Coastal Leasing Corp. v. O'Neal*, 103 N.C.App. 230, 405 S.E.2d 208 (1991) (finding a privity exception under North Carolina law for implied warranty claims where the plaintiff is an alleged third-party beneficiary); *see also LSB Fin. Servs. v. Harrison*, 144 N.C.App. 542, 548, 548 S.E.2d 574, 579 (2001); *Murray v. Nationwide Mut. Ins. Co.*, 123 N.C.App. 1, 15, 472 S.E.2d 358, 366 (1996).

[30] *Bobb Forest Products, Inc. v. Morbark Industries, Inc.*, 151 Ohio App.3d 63, 84, 783 N.E.2d 560, 576 (2002) (finding that an end consumer has "privity of contract with the manufacturer if that consumer is an intended third-party beneficiary to a contract... one for whose benefit a promise is made, but who is not a party to the contract encompassing the promise" and concluding "...then that third party is an 'intended beneficiary' who has enforceable rights under the contract").

[31] *Hermansen v. Tasulis*, 48 P.3d 235, 240 (Utah 2002).

[32] *Tex Enterprises, Inc. v. Brockway Standard, Inc.*, 149 Wash. 2d 204, 210, 66 P.3d 625, 628 (Was. 2003) (*en banc*) (distinguishing the *Bough* case [cited by the Manufacturer defendants and stating "[w]e conclude that *Touchet Valley* carved a third-party beneficiary exception out of the general rule that a vertical nonprivity plaintiff cannot recover from a remote manufacturer for breach of implied warranty").

consumed (e.g., foodstuffs or pharmaceuticals) (Connecticut[33], New York[34]); or (4) where the plaintiff only seeks direct (as opposed to consequential) economic loss damages (Virginia[35]). The applicability of these privity exceptions is a fact question that cannot be resolved at this stage. And for some of these states listed by the Manufacturer Defendants (Nevada, Virginia, Washington), even Defendants cannot agree as to the law: Wholesaler Defendants disagree with Manufacturer Defendants' assessment that they require privity for implied warranty economic loss claims. *Compare* ECF 520-5, at 38-39 *with* ECF 522-2, at 17-18.

Incredibly, Manufacturer Defendants even argue a failure to plead pre-suit notice in the Master Complaints for a number of states for both express and implied warranty claims. The Master Complaints are administrative documents prepared at the direction of the Court. Defendants fail to argue that the underlying complaints insufficiently allege pre-suit notice when numerous Plaintiffs provided just such notice to some or all defendant groups on a broad enough basis to cover all claims supposedly requiring pre-suit notice. *See, e.g.*, Ex. 1 (pre-suit notice letters). The sufficiency of these letters is a fact question inappropriate for resolution on the pleadings.

---

[33] *Hamon v. Digliani*, 174 A.2d 294, 297–98 (Conn. 1961) (recognizing an exception to implied warranty privity requirements stating that a "manufacturer or producer who puts a commodity for personal use or consumption on the market in a sealed package or other closed container should be held to have ***impliedly warranted to the ultimate consumer*** that the product is reasonably fit for the purpose intended and that it does not contain any harmful and deleterious ingredient of which due and ample warning has not been given … Lack of privity is not a bar to suit under these circumstances.") (emphasis added).

[34] *Addeo v. Metro. Bottling Co.*, 241 N.Y.S.2d 120 (N.Y. App. Div. 1st Dep't 1963) (recognizing implied warranty privity exception when food products or medicines are the subject of the claim).

[35] *RML Corp. v. Lincoln Window Prods., Inc.*, 67 Va. Cir. 545 (Va. Cir. Ct. – Norfolk Dec. 3, 2004) (citing Va. Code Ann. § 8.2-318 and distinguishing from *Beard*); *see also Beard Plumbing and Heating, Inc. v. Thompson Plastics, Inc.*, 491 S.E. 2d 731, 734 (Va. 1997) (leaving open whether privity is required for breach of implied warranties seeking only direct damages).

Principles of equitable estoppel prevent Manufacturer Defendants from making any argument regarding pre-suit notice, because they issued ***voluntary*** recalls of their VCDs. The fact of these voluntary recalls – well before any lawsuits – demonstrate Manufacturer Defendants obviously had pre-suit notice their VCDs were adulterated rendering them non-merchantable and in violation of express warranties made. As part of their obligations under the DSCSA, wholesalers and retailers also had to implement recall procedures for VCDs and thus were also obviously on notice of the issues giving rise to breach of warranty claims. *See, e.g.*, *Martin v. Ford Motor Co.*, 765 F. Supp. 2d 673, 683 (E.D. Pa. 2011) (amended complaint adequately alleged defendant had notice of issue). In other words, Defendants listed in the operative Master Complaints received pre-suit notice.

Further, as to the Wholesaler Defendants, as discussed in the context of express warranties, Wholesaler Defendants are just as liable for the implied warranties based on indemnification agreements alleged to exist, as well as on agency principles of liability.

3. The Master Complaints Adequately Plead Unjust Enrichment

There can be no dispute that Plaintiffs' unjust enrichment claims under the law of the 50 states and territories can be generally summarized as the following: the unjust retention of a benefit received at the expense of another. In the Master Complaints, Plaintiffs cognizably plead that Defendants received a benefit in the form of money for their adulterated VCDs. *See, e.g.*, PIMC ¶¶ 9, 12, 19, 126-128; ELMC ¶¶ 9-10, 43-44, 82, 109, 111, 146, 546-557; MMMC ¶¶ 7, 55, 89, 96. This money ultimately derived from Plaintiffs. *See, e.g.*, PIMC ¶¶ 2, 9, 386; ELMC ¶¶ 11-34, 36-47, 548-550, 556; MMMC ¶¶ 8, 55, 137-140. Absent Defendants' conduct, Plaintiffs could have used their money to purchase non-adulterated, non-misbranded, cGMP-compliant valsartan. *See, e.g.*, PIMC ¶¶ 355, 456; ELMC ¶¶ 3-4, 11-34, 350, 366; MMMC ¶¶ 2-3, 328, 332. Defendants not only accepted this money but, in perpetrating and concealing their wrongful acts, they retained

this money. *See, e.g.*, PIMC ¶¶ 402, 404-410; ELMC ¶¶ 407-412, 550, 556; MMMC ¶¶ 477-487. These allegations adequately plead unjust enrichment.

In light of the harmony of the unjust enrichment claims among the 50 states, Defendants spend the bulk of their argument parsing whether the unjust enrichment claims must be dismissed because of Plaintiffs' alleged failure to plead the absence of an adequate remedy at law (and, by logical extension, the availability of an adequate remedy at law under the law of certain of the 50 states). However, Plaintiffs are entitled to plead two or more statements of a claim or defense in the alternative or hypothetically, either in a single count or defense or in separate ones. Fed. R. Civ. P. 8(d)(2). Plaintiffs are allowed to state as many separate claims or defenses as they have, regardless of consistency. *Id.* at (d)(3); *see also, e.g.*, *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517, 544 (D.N.J. Sept. 2004) (Greenaway, J.) (plaintiffs "are clearly permitted to plead alternative theories of recovery," including unjust enrichment and parallel remedies at law).

Additionally, Plaintiffs' unjust enrichment remedies and common law claims are not duplicative claims, *see* Mfr. Br. at 50, despite relying on some of the same factual predicates. To the contrary, an unjust enrichment claim can be an alternatively pleaded theory even if it is premised on the same factual predicates. *See In re Santa Fe Nat. Tobacco Co. Mktg. & Sales Practices & Prod. Liab. Litig.*, 288 F. Supp. 3d 1087, 1257 (D.N.M. 2017) (concluding that an unjust enrichment claim can be an alternative theory even if it is premised on the same factual predicates); *see also In re Ford Tailgate Litig.*, No. 11-2953, 2014 WL 1007066, at *5 (N.D. Cal. March 12, 2014) ("[W]here the unjust enrichment claim relies upon the same factual predicates as a plaintiff's legal causes of action, it is not a true alternative theory of relief, but rather is duplicative of those causes of action.") (citing *Licul v. Volkswagen Grp. of Am., Inc.*, No. 13-61686, 2013 WL 6328734, at *7 (S.D. Fla. December 5, 2013)). Indeed, here, Plaintiffs' unjust enrichment claims

focus on Defendants' ill-gotten gains, whereas Plaintiffs' common law tort theories focus on Plaintiffs' loss. *See In re Light Cigarettes Marketing Sales Practices Litig.*, 751 F.Supp.2d 183, 192 n.11 (D. Me. 2010); *Harris Grp., Inc. v. Robinson*, 209 P.3d 1188, 1205 (Colo. Ct. App. 2009). This distinction is divergent enough to amount to an alternative theory under Rule 8. *In re Santa Fe Nat. Tobacco Co. Mktg. & Sales Practices & Prod. Liab. Litig.*, 288 F. Supp. 3d 1087, 1257 (D.N.M. 2017).

Plaintiffs may therefore plead both equitable and legal relief, even if they may not, under state law, ultimately recover under both theories. *In re Santa Fe Nat. Tobacco Co. Mktg. & Sales Practices & Prod. Liab. Litig.*, 288 F. Supp. 3d 1087, 1259 (D.N.M. 2017); *see, also In re Dial Complete Marketing & Sales Practices Litig.,* 2013 WL 1222310, at *8-9 (D.N.H. Mar. 26, 2013) ("[C]onsistent with Federal Rules, Plaintiffs have simply pled their claims in the alternative ... the mere fact that plaintiffs have pled arguable inconsistent theories is not, standing alone, a sufficient basis to dismiss one of those claims."); *In re Light Cigarettes Marketing Sales Practices Litig.*, 751 F. Supp. 2d at 192 ("At this stage, the Plaintiffs may assert multiple and duplicative legal and equitable claims for relief."); *In re Celexa and Lexapro Marketing & Sales Practices Litig.*, 751 F. Supp. 2d 277, 297 (D. Mass. 2010) ("[I]t is inappropriate to dismiss equitable remedies at the pleading stage on this basis. Under the Federal Rules of Civil Procedure, plaintiffs have the prerogative to plead alternative and even conflicting theories."); *In re K–Dur Antitrust Litig.*, 338 F. Supp. 2d at 544 ("Plaintiffs, however, are clearly permitted to plead alternative theories of recovery. Consequently, it would be premature at this stage of the proceedings to dismiss the . . . unjust enrichment claims on this basis.").

Defendants also argue that Plaintiffs' claims fail because Plaintiffs failed to confer a direct benefit to Defendants, and attempt to conflate the notion of a direct benefit with almost a heightened privity standard. However, this is completely unmoored from the reality that unjust

enrichment is a claim predicated on a quasi-contract, and, by its very definition, is inapplicable where a written or express contract exists. *Rahemtulla v. Hassam*, 539 F. Supp. 2d 755, 780 (M.D. Pa. 2008). Defendants also conflate the notion of a direct benefit with the direct *conferral* of that benefit. However, for many states which do require a direct benefit,[36] these jurisdictions do not

[36] Plaintiffs note that the following states do not require a direct benefit at all: **Arkansas** (*Thompson v. Bayer Corp.,* 2009 WL 362982, at *5 (E.D. Ark. Feb. 12, 2009) ("[A]lthough the enrichment to the defendant must be at the expense of the plaintiff, the enrichment need not come directly from the plaintiff. The enrichment may come from a third party.")); **California** (*St. Paul Fire & Marine Ins. Co v. Insurance Co. of the State of Pennsylvania*, 2016 WL 1191808, at *7 (N.D. Cal. Mar. 28, 2016) ("[C]laims based upon unjust enrichment do not depend upon a direct contractual duty between the [parties]."")); **Colorado** (*Robinson v. Colorado State Lottery Div.*, 179 P.3d 998, 1007 (Colo. 2008) (holding unjust enrichment "does not depend in any way upon a promise or privity between the parties")); **Connecticut** (*Bank of New York Mellon v. Fidelity National Title Ins. Co.*, 2013 WL 5663263, at *4 (Conn. Super. Ct. Sept. 20, 2013) ("The elements of a cause of action for unjust enrichment [] do not include a contractual privity requirement.")); **District of Columbia** (*Minebea Co. v. Papst*, 444 F.Supp.2d 68, 186 (D.D.C. 2006)); **Hawaii** (*Joslin v. Ota Camp-Makiba Ass'n*, 2019 WL 1500008, at *9-10 (Haw. Ct. App. Apr. 5, 2019) (plaintiff "conferred a benefit upon [defendant] by causing [an insurer] to issue an undisputed payment")); **Illinois** (*Muehlbauer v. General Motors Corp*., 431 F. Supp. 2d 847, 853 (N.D. Ill. 2006) (noting that "an unjust enrichment claim may be premised on an indirect conferral of benefits")); **Indiana** (*DiMizio v. Romo*, 756 N.E.2d 1018, 1025 (Ind. Ct. App. 2001) ("The issues of unjust enrichment and conferring a benefit arise in the context of a constructive contract")); **Iowa** (*State ex rel Palmer v. Unisys Corp*., 637 N.W.2d 142, 155 (Iowa 2001) ("We have never limited [unjust enrichment] to require the benefits to be conferred directly by the plaintiff.")); **Kansas** (*Gonzalez v. Pepsico, Inc.*, 489 F. Supp. 2d 1233 (D. Kan. 2007) ("A claim for unjust enrichment under Kansas law . . . does not depend on privity")); **Kentucky** (*Muncy v. InterCloud Sys., Inc.*, 92 F. Supp. 3d 621, 643 (E.D. Ky. 2015) ("[U]nder Kentucky law, the benefit the plaintiff confers can be either direct or indirect.")); **Louisiana** (*United Disaster Response, LLC v. Omni Pinnacle, LLC*, 2009 WL 901763, at *6 (E.D. La. Mar. 25, 2009) ("Lack of privity does not automatically bar recovery under a theory of unjust enrichment. In fact, the Louisiana Court of Appeal, Fourth Circuit… held the 'absence of a contract' and the resultant 'lack of privity' to be 'prerequisites to recovery in unjust enrichment'")); **Maine** (*Aladdin Elec. Assocs. v. Town of Old Orchard Beach*, 645 A.2d 1142, 1144 (Me. 1994) ("Lack of privity of contract…do[es] not bar an action for unjust enrichment.")); **Maryland** (*Bank of America Corp. v. Gibbons*, 918 A.2d 565, 571 (Md. Ct. Spec. App. 2007) ("[A] cause of action for unjust enrichment may lie against a transferee with whom the plaintiff had no contract, transaction, or dealing, either directly or indirectly")); **Massachusetts** (*Massachusetts v. Mylan Labs.*, 357 F. Supp. 2d 314, 323 (D. Mass. 2005) ("Unjust enrichment does not require any contractual or fiduciary relationship between the parties. Unjust enrichment does not require that a defendant receive direct payments from a plaintiff.")); **Mississippi** (*In re B.C. Rogers Poultry, Inc*., 455 B.R. 524, 569 (S.D. Miss. 2011)); **Missouri** (*Cromeans v. Morgan Keegan & Co.*, 2013 WL 12129609, at *7 (W.D. Mo. Nov. 5,

necessarily require, as a matter of law, that Plaintiffs prove they directly conferred that benefit upon Defendants in order to maintain an unjust enrichment claim.

Additionally, Defendants attempt to argue that unjust enrichment claims fail, as a matter of law, when there are significant questions requiring a fully developed factual record to assess. For example, Defendants claim that unjust enrichment claims under New York law must be dismissed because the claims were too attenuated to confer a direct benefit. However, attenuation, as explained by the Courts interpreting New York law, might mean that a product's indirect purchaser cannot assert an unjust enrichment claim against an entity that manufactured one of that

---

2013) ("There does not appear to be any bright line rule regarding how directly the defendant must have received a benefit at the plaintiff's expense. Rather, a claim for unjust enrichment must be considered in light of the totality of the circumstances.")); **Montana** (*Northern Cheyenne Tribe v. Roman Catholic Church ex rel. Dioceses of Great Falls/Billings*, 296 P.3d 450, 457 (Mont. 2013) (plaintiff Tribe permitted to recover "benefits conferred upon [defendant]...by third party donors moved by the plight of [plaintiff Tribe]")); **Nevada** (*USACM Liquidating Tr. v. Monaco*, 2010 WL 11579643, at *3 (D. Nev. Jan. 27, 2010) ("An indirect benefit will support an unjust enrichment claim."); **New Hampshire** (*Pella Windows and Doors, Inc. v. Faraci*, 580 A.2d 732, 732-33 (N.H. 1990) ("Where...no express contractual relationship exists between the parties, a trial court may require an individual to make restitution for unjust enrichment if he has received a benefit that would be unconscionable to retain")); **New Mexico** (*Abraham v. WPX Energy Production*, L.L.C., 20 F.Supp.3d 1244, 1266 (D.N.M. 2014) ("the theory [of unjust enrichment] has evolved largely to provide relief...in the absence of privity")); **New York** (*Hughes v. Ester C Co.,* 930 F. Supp. 2d 439, 471 (E.D.N.Y. 2013) ("Under New York law, unjust enrichment does not require a direct relationship between the parties.")); **North Carolina** (*Metric Constructors, Inc. v. Bank of Tokyo-Mitsubishi, Ltd.*, 72 F. App'x. 916, 921 (4th Cir. 2003) ("Under North Carolina law, it is sufficient for a plaintiff to prove that it has conferred some benefit on the defendant, without regard to the directness of the transaction.")); **Oregon** (*Marchione v. Playboy Enterprises, Inc.,* 2013 WL 876263 at *2 (D. Or. Mar. 7, 2013) (rejecting "the idea that a benefit must be conferred directly from the plaintiff to the defendant to support a claim for unjust enrichment"); **Rhode Island** (*In re TFT-LCD (Flat Panel) Antitrust Litig.*, 2011 WL 4501223, at *11 (N.D. Cal. Sept. 28, 2011) (rejecting defendant's argument that plaintiff must show they directly conferred a benefit on defendant to plead unjust enrichment under Rhode Island law)); **South Dakota** (*Dowling Family Partnership v. Midland Farms*, 865 N.W.2d 854, 857, 863 (S.D. 2015) ("benefit" element of unjust enrichment claim satisfied by defendants "receiving the proceeds from a winter wheat crop planted [by and] at the partial expense of a third party")); **Tennessee** (*Freeman Industries, LLC v. Eastman Chemical Co.*, 172 S.W.3d 512, 525 (Tenn. 2005) ("A plaintiff need not be in privity with a defendant to recover under a claim of unjust enrichment.")); and **Vermont** (*Gingras v. Rosette*, 2016 WL 2932163, at *26 (D. Vt. May 16, 2016) (declining to dismiss an unjust enrichment claim based on an indirect benefit)).

product's ingredients, but that an "indirect purchaser can assert such an unjust enrichment claim against the manufacturer of the product itself." *Waldman v. New Chapter, Inc.,* 714 F.Supp.2d 398, 403-04 (E.D.N.Y. 2010). Consequently, the question of attenuation (and the Court's assessment of whether the benefit is too attenuated) is one that must be analyzed in light of a fully developed factual record. As such, even if Plaintiffs failed to allege facts that would support a direct benefit, "such a deficit is not in and of itself fatal to a New York unjust enrichment claim *as a matter of law*." *In re Processed Egg Prod. Antitrust Litig.,* 851 F. Supp. 2d 867, 930 (E.D. Pa. 2012) (emphasis added) (discussing New York law).

While Defendants assert in a conclusory fashion that Florida law requires a direct benefit be conferred, Florida courts have found that a plaintiff and a defendant need not even have direct interactions in order for a benefit to be conferred. *See Variety Children's Hosp. v. Vigliotti,* 385 So.2d 1052, 1053-54 (Fla. Dist. Ct. App. 1980); *Merkle v. Health Options, Inc.,* 940 So.2d 1190, 1199 (Fla. Dist. Ct. App. 2006) (concluding that a medical service provider plaintiff had an unjust enrichment claim against HMO defendants for medically treating the HMOs' subscribers). More critically, Florida allows unjust enrichment claims to arise even from the conferral of an indirect benefit. Indeed, Florida courts have even found that unjust enrichment claims can be maintained with a contract implied in law, even where the parties had no dealings at all with each other. *See Commerce P'ship 8098 LP v. Equity Contracting Co.,* 695 So.2d 383, 386 (Fla. Dist. Ct. App. 1997). These examples highlight the inappropriateness of dismissing unjust enrichment claims prior to discovery, which further define the nature of the benefit conferred.

For their part, Wholesaler Defendants argue that unjust enrichment claims against them must be dismissed because they assert, without an iota of support, that the theories of innocent seller or faultless recipient defenses to products liability claims are somehow applicable to unjust

enrichment. However, here, for a claim rooted in quasi-contract – the issue is simply whether Wholesaler Defendants retained an unjust benefit at the expense of another. Wholesaler Defendants ignore the purpose of motion to dismiss briefing – which is to assess whether Plaintiffs have adequately plead that Wholesaler Defendants retained an unjust benefit at the expense of Plaintiffs. Plaintiffs have met that burden. Further, whether Wholesaler Defendants are entitled to some form of defense, such as this ostensible innocent or faultless recipient defense, is ultimately a question of fact that must be fully developed through discovery. Whether Wholesaler Defendants are liable for anything more than "reimbursement for the specific cost of the drugs paid by customers" is likewise a fact question. *See Abels v. JPMorgan Chase Bank, N.A.*, 678 F. Supp. 2d 1273, 1279 (S.D. Fla. 2009) ("Although the term 'benefit' has not been specifically defined by Florida courts, if Plaintiffs have alleged that they conferred a benefit, whether a benefit was actually conferred is a factual question that cannot be resolved on a motion to dismiss."). Courts have found that "evaluating an unjust enrichment claims is "heavily fact-dependent, 'for whether there has been unjust enrichment must be determined by the nature of the dealings between the recipient of the benefit and the party seeking restitution, and those dealings will necessarily vary from one case to the next." *Chen v. Bell–Smith,* 768 F. Supp. 2d 121, 151–52 (D.D.C. 2011). Evaluating Plaintiffs' unjust enrichment claims requires a fully developed factual record and cannot be fully evaluated on a motion to dismiss.

4. The Master Complaints Adequately Plead Negligence and Negligence *Per Se* Claims

a. Manufacturer Defendants

It is without doubt that Plaintiffs[37] cognizably plead conduct which would give rise to state law negligence and negligence *per se* claims against Manufacturer Defendants. *See* ELCC ¶¶ 585-592; *see also* PIMC ¶¶ 4-10; MMMC ¶¶ 5-8. These include claims that Manufacturer Defendants failed to comply with their duties to manufacture a drug that is of the safety and purity they represented it to be,[38] failed to comply with their ongoing duties of sameness,[39] failed to provide accurate information regarding their manufacturing facilities and the quality assurance functioning intended to prevent contaminated and adulterated drug products from entering the market,[40] failed to comply with their duties to investigate potentially illegitimate product,[41] and failed to comply with their obligations to manufacture their drug products using good manufacturing practices in a manner such that they are in compliance with their duties under state law.

Defendants argue that Plaintiffs negligence *per se* claims predicated on the FDCA and the DSCSA are preempted or otherwise not permitted under certain state law claims. However, Courts make clear that violations of the FDCA or other regulations regarding the sale of prescription drugs may constitute negligence *per se* under state law. *See, e.g.*, *In re Orthopedic Bone Screw Prod.*

---

[37] 1996) (finding that the FDCA was intended to "to provide for the safety and effectiveness of medical devices intended for human use."). Plaintiffs, as the ultimate consumer of regulated prescription drug products, are obviously the class of persons the statutes were designed to protect. *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

[38] ELMC ¶¶ 585-592.

[39] *Id.* ¶¶ 192-195; *see also id.* ¶¶ 201-204.

[40] *Id.* ¶¶ 196-198; *see also id.* ¶¶ 201-204.

[41] *Id.* ¶¶ 158-161.

Liab. Litig., 193 F.3d 781, 790 (3d Cir. 1999). The doctrine of *per se* liability does not create an independent basis of tort liability but rather establishes, by reference to a statutory scheme, the standard of care appropriate to the underlying tort. *See, e.g., Grove Fresh Distribs., Inc. v. Flavor Fresh Foods, Inc.,* 720 F. Supp. 714, 716 (N.D. Ill. 1989) ("Grove Fresh relies on the FDA regulation merely to establish the standard or duty which defendants allegedly failed to meet. Nothing prohibits Grove Fresh from using the FDCA or its accompanying regulations in that fashion."); *Stanton by Brooks v. Astra Pharm. Prods., Inc.,* 718 F.2d 553, 564 n. 22 (3d Cir. 1983) (noting, in the FDCA context, that "Pennsylvania law views a statutory violation as conclusive evidence of negligence, in the absence of an excuse for that violation…").

Plaintiffs' common law negligence *per se* claims relate to the duties Defendants owed to Plaintiffs and are predicated on well-established state common law duties which predate the implementation of the FDCA and "do not necessarily depend on violations of the requirements imposed under the statute." *Lempa v. Eon Labs, Inc.,* No. 18 C 3821, 2019 WL 1426011, at *4 (N.D. Ill. Mar. 29, 2019). Rather, evidence demonstrating the violation of federal law "goes a long way toward showing that the manufacturer breached a duty under state law toward the patient." *Bausch v. Stryker Corp.*, 630 F.3d 546, 557 (7th Cir. 2010).

Defendants also overlook the fact that some of Plaintiffs' claims are premised on Defendants' failure to comply with cGMPs (and state analogues). This failure to comply with cGMPs, and the state-law corollaries (or incorporations thereof), resulted in the manufacture of VCDs contaminated with NDMA or other nitrosamines. Plaintiffs' negligence claims predicated on the cGMPs are consequently not preempted because they do not impose a legal standard different from, or in addition to, federal requirements." *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 494-495 (1996). Additionally, Defendants' failure to comply with cGMPs, as identified in the countless inspections and reports (including failure to investigate aberrant peaks, failure to

adequately document manufacturing changes, and failure to adequately access chemical processes) is precisely the reason why Plaintiffs purchased adulterated Valsartan that contained NDMA.[42]

In assessing negligence claims similar to those alleged here, many courts have found that, at the 12(b)(6) pleading stage, a "key distinction between complaints that are sufficient to withstand a motion to dismiss and those that are not is not reliance on cGMPs, but rather the existence of a manufacturing defect caused by a violation of federal regulations and allegations connecting a defect in the manufacture of the specific device to that plaintiff's specific injury." *Bass v. Stryker Corp.*, 669 F.3d 501, 512 (5th Cir. 2012); *see also Wolicki–Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301–02 (11th Cir. 2011) (affirming summary judgment but stating that a complaint is adequate if it "set[s] forth any specific problem, or failure to comply with any FDA regulation that can be linked to the injury alleged" (internal quotation marks omitted)). Plaintiffs have met this burden at the 12(b)(6) stage.

Manufacturer Defendants' failure to adequately test the product also gives rise to a standalone negligence claim. *See, e.g., Burton v. R.J. Reynolds Tobacco Co.*, 208 F. Supp. 2d 1187, 1207 (D. Kan. 2002) ("[A] plaintiff may properly bring a negligence claim based on the breach of a manufacturer's duty to test as an independent tort."); *Atkinson v. Luitpold Pharm., Inc.*, No. CV

[42] Using just Defendant ZHP as one such example, the FDA documented ZHP's failure to comply with cGMPs in investigating aberrant results, which allowed NDMA contaminated VCDs to remain on the market for years. ZHP's API manufacturing change in 2011 resulted in an onslaught of noticeable and documented quality issues, many of which went uninvestigated. Indeed, from 2016 to 2018, 22 batches of API were rejected and/or returned by customers because they failed to meet specifications and/or were presenting with aberrant testing. *See* ECF 296 at 5. From January 22, 2016 to June 29, 2017 alone, there were 17 out-of-specification ("OOS") investigations regarding one particular batch of valsartan API. *Id.* at 29. These investigations were never successfully resolved. *Id.* This batch, it would later turn out, had been contaminated with genotoxic impurity the entire time. *Id*. When confronted with these rejected, refused, an/or OOS batches, instead of conducting a root cause analysis, ZHP simply re-processed the raw material and sold it to other customers. *Id.* at 27-28.

19-277, 2020 WL 1330705, at *9 (E.D. Pa. Mar. 23, 2020) ("[I]n Texas there is an independent cause of action based on negligent failure to test.").

a. Wholesaler and Retail Pharmacy Defendants

Despite exhortations to the contrary, Wholesaler Defendants and Retail Pharmacy Defendants breached their common law duties to appropriately vet their generic manufacturer suppliers to ensure that they did not sell adulterated, misbranded and/or contaminated product. As Courts have previously held, whether it is reasonably foreseeable that a wholesaler's or retailer's distribution practices would result in the sale of adulterated or misbranded drugs is ultimately "a question of fact which cannot be determined at the pleading stage." *Fagan v. AmerisourceBergen Corp.*, 356 F. Supp. 2d 198, 211 (E.D.N.Y. 2004) (refusing to dismiss negligence claim against AmerisourceBergen for the sale of misbranded drug).

Retail Pharmacy Defendants' attempt to recast their alleged duties as simply a "duty to test" drugs misses the mark. The Master Complaints do not allege Retail Pharmacy Defendants' only duty is to test drugs they sell. Rather, under states' common law, much like other retailers, Retail Pharmacy Defendants have a duty to use due and proper care in filling prescriptions and selling products to the public. *See, e.g.*, *Arrington v. Walgreen Co.*, 664 F. Supp. 2d 1230, 1233 (M.D. Fla. 2009) (under Florida law, pharmacy may be liable for negligence for failure to use due and proper care in filling prescriptions, even if prescription is filled in accordance with physician's instructions).

For instance, in *Arrington*, Walgreens argued it was not liable for dispensing a drug at all. The court rejected this notion and denied Walgreens' motion to dismiss:

> Walgreens would have this Court interpret a pharmacist's duty to use "due and proper care in filling the prescription" as being satisfied by a robotic compliance with the instructions of the prescribing physician. In Walgreens' view, so long as the paperwork is in order, and so long as the drug going out the door matches the drug prescribed, the pharmacist (and, by extension, Walgreens) cannot face

> liability. However, none of the cases cited by Walgreens go this far. And though the law in this area is far from settled, two Florida Courts of Appeal have rejected this contention.

664 F. Supp. 2d at 1232-33. Walgreens and its fellow Retail Pharmacy Defendants would have this Court adopt the same "robotic compliance" argument which failed before. That is, Retail Pharmacy Defendants contend that, if a physician writes prescription for "valsartan," and they filled the prescription with any "valsartan," they are able to stock, they are completely immune from any liability because they mechanically followed the physician's prescription. This narrow view ignores the fact that a pharmacy can still be found negligent in such circumstances. This Court should reject this unduly narrow argument, as did the *Arrington* court. *Id.*; *see also, e.g.*, *In re Welspun Litig.*, No. 16cv-6792, 2019 WL 2174089, at *19 (S.D.N.Y. May 20, 2019) (denying in part motion to dismiss filed by retailers who were alleged to have sold falsely labeled bed linens); *O'Neill v. Standard Homeopathic Co.*, 346 F. Supp. 3d 511 (S.D.N.Y. Sept. 28, 2018); *Kurtz v. Kimberly-Clark Corp.*, 321 F.R.D. 482 (E.D.N.Y. 2017) (certifying class claims against manufacturers and retailers for selling falsely labeled 'flushable' moist toilet wipes), *rev'd on other grounds*, 768 Fed. Appx 39 (2d Cir. 2019); *Fagan v. AmerisourceBergen Corp.*, 356 F. Supp. 2d 198 (E.D.N.Y. 2004) (consumer stated negligence claim against distributor and pharmacy for sale of counterfeit drugs); *Dunn v. Kanawha County Bd. Educ.*, 459 S.E.2d 151, 157 (W. Va. 1995) (all entities in chain of distribution may be liable under negligence theory).

The same is true for Wholesaler Defendants. Their liability does not turn on whether the contamination was so "microscopic" they could not have noticed it with the naked eye, *see* Wholesaler Br. at 7, or that they might not open packages and test the drugs they buy and then re-sell downstream, *see id.* at 5-6. Rather, as with Retail Pharmacy Defendants, Wholesaler Defendants had duties to exercise reasonable care in their acquisition and re-sale of products which they independently represented was saleable, non-adulterated, non-misbranded, cGMP-compliant

valsartan. They breached their duties in selling contaminated VCDs instead. These facts plausibly state negligence claims against Wholesaler Defendants. *See, e.g.*, *Fagan*, 356 F. Supp. 2d at 206-08; *Dunn*, 459 S.E.2d at 157.

Defendants' arguments that the economic loss rule precludes negligence claims in the ELCC and MMMC are similarly unpersuasive. First, while Defendants have included a chart which they argue delineates the states that that have an economic loss rule precluding recovery for economic damages, they purposefully ignore that many states which follow the economic loss rule actually carve out notable exceptions to the rule. These fact-based exceptions include questions such as the existence of a special relationship, the existence of independent duties, exceptions regarding public safety, and special circumstances which require a reallocation of risk, and where the economic loss was caused by a negligent misrepresentation by the Defendant in the business of supplying information for the guidance of others in business transactions. *In re Target Corp. Data Sec. Breach Litig.*, 66 F. Supp. 3d 1154, 1173 (D. Minn. 2014) (collecting states and cases); *see also* Pls.' Appx. Each of these questions about whether Plaintiffs' economic loss claims would fall into one of the many delineated exceptions articulated by states which have an economic loss rule for negligence claims are intensive factual determinations which make dismissal premature at the 12(b)(6) stage. *Id.*

5. The Master Complaints Adequately Plead Fraud Claims

To prevail on a claim of common law fraud in New Jersey, Plaintiffs must show that Defendants: "(1) made a representation or omission of a material fact; (2) with knowledge of its falsity; (3) intending that the representation or omission be relied upon; (4) which resulted in reasonable reliance; and that (5) plaintiff suffered damages." *DepoLink Court Reporting & Litig. Support Servs. v. Rochman*, 430 N.J. Super. 325, 336 (App. Div. 2013). Other states laws require identical elements. *See, e.g.*, *DeAngelis v. Corzine*, 17 F. Supp. 3d 270, 280–81 (S.D.N.Y. 2014)

("The elements of common law fraud under New York law are: (1) a material representation or omission of fact; (2) made with knowledge of its falsity; (3) with scienter or an intent to defraud; (4) upon which the plaintiff reasonably relied; and (5) such reliance caused damage to the plaintiff."); *RD & J Properties v. Lauralea-Dilton Enterprises, LLC*, 165 N.C. App. 737, 744-45 (2004) ("The essential elements of actionable fraud are: (1) [f]alse representation or concealment of a material fact, (2) reasonably calculated to deceive, (3) made with intent to deceive, (4) which does in fact deceive, (5) resulting in damage to the injured party."); *Probir K. Bondyopadhyay, et al., v. The Bank of New York Mellon,* 2020 WL 4676765, at *4 (S.D. Tex. Aug. 11, 2020) (quoting *Formosa Plastics Corp. v. Presidio Eng'rs & Contractors, Inc.*, 960 S.W.2d 41, 47-48 (Tex. 1998)) ("The Texas Supreme Court has held that '[a] fraud cause of action requires 'a material misrepresentation, which was false, and which was either known to be false when made or was asserted without knowledge of its truth, which was intended to be acted upon, which was relied upon, and which caused injury.'").

Indeed, all states laws are essentially the same in consumer class actions alleging common law fraud. As one court explained, "all states (except Louisiana and North Dakota which only have statutory fraud claims) recognize black letter common law fraud in the sales context: a representation intended to be relied on by the customer, which results in purchase of the product, where the supplier knows the representation is untrue." *Steigerwald v. BHH, LLC*, 2016 WL 695424, at *8 (N.D. Ohio Feb. 22, 2016); *Hart v. BHH, LLC*, 2017 WL 2912519, at *8 (S.D.N.Y. July 7, 2017) (certifying nationwide fraud class).

Pursuant to Fed. R. Civ. P. 9(b), fraud claims must be plead with particularity. To satisfy this standard, the allegations must contain "the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where and how of the events at issue." *In re Rockefeller Ctr. Properties, Inc. Sec. Litig.*, 311 F.3d 198, 217 (3d Cir.

2002) (citation and quotation marks omitted); *Morganroth & Morganroth v. Norris, McLaughlin & Marcus, P.C.*, 331 F.3d 406, 414 n.2 (3d Cir. 2003) ("The purpose of Rule 9(b) is to provide notice, not to test the factual allegations of the claim."). "As several courts have noted, Rule 9(b)'s 'heightened standard is somewhat relaxed in a case based on a fraudulent omission,' rather than one based on misrepresentation." *Majdipour v. Jaguar Land Rover N. Am., LLC*, 2013 WL 5574626, at *15 (D.N.J. Oct. 9, 2013) (Walls, J.) (quoting *Montich v. Miele USA, Inc.*, 849 F. Supp. 2d 439, 451 (D.N.J. 2012) (Wolfson, J.)); *Feldman v. Mercedes–Benz USA, LLC*, 2012 WL 6596830, at *10 (D.N.J. Dec.18, 2012) (Martini, J.) ("[P]laintiffs pleading a fraud by omission claim are not required to plead fraud as precisely as they would for a false representation claim.").

b. Manufacturer Defendants

The Master Complaints adequately allege the elements of fraud as to the Manufacturer Defendants. Specifically, the Master Complaints allege that:

- each Manufacturer Defendant (the "who"), *see, e.g.*, PIMC ¶¶ 5-12; ELMC ¶¶ 48-72, MMMC ¶¶ 20-44;
- deliberately cut corners in their manufacture of valsartan API or finished-dose for their VCDs, and failed to adhere to cGMP and industry standards of care for the manufacture and testing of prescription drugs, resulting in adulterated or misbranded VCDs (the "what") being manufactured at their facilities (the "where"), *see, e.g.*, PIMC ¶¶ 188, 192-195, 199, 200, 266, 271, 272, 278, 283; ELMC ¶¶ 233-311; MMMC ¶¶ 298-311;
- for the time periods for which each Manufacturer Defendant's VCDs were available in the United States market (the "when" and additional "where"), *see, e.g.,* PIMC ¶¶ 195, 283-285, 297, 300, 331, 346, 350-355, 391, 414-418, 424; ELMC ¶¶ 321, 338-353; MMMC ¶¶ 186-265;
- for the purpose of duping consumers and TPPs into paying for contaminated VCDs that were essentially worthless and otherwise unable to be sold in the United States, to illegally boost their own profits (the "why"), *see, e.g.*, PIMC ¶¶280, 303; ELMC ¶¶ 153, 246, MMMC ¶ 199.

For instance, as the Master Complaints set forth in detail, dating back at least as early as 2007 ZHP had a documented history of cGMP violations at the manufacturing plant at which it

made valsartan API for its VCDs. *See, e.g.*, ELMC ¶¶ 237-238. Subsequent FDA investigations revealed similarly startling violations which compromised ZHP's ability to properly employ standards and testing to "'assure that drug products conform to appropriate standards of identity, strength, quality, and purity.'" *Id.* ¶ 239 (quoting FDA inspection report); *see also id.* ¶¶ 240-248. Not only that, but the FDA's after-the-fact investigation revealed that ZHP was aware of aberrant test results for its valsartan API, suggesting NDMA, in its product "as early as 2012." *Id.* ¶ 245.

Notwithstanding all of this, ZHP deliberately failed to take any corrective or remedial action, let alone disclosure its failures to the public. *Id.* ¶¶ 250-251. ZHP's motivation was transparent: its documented problems date back to a valsartan API process change, the purpose of which the FDA found was "[ZHP's] intention" to "increase product yield, and lower production costs." *Id.* ¶ 246. In other words, ZHP implemented a process change to make more product and profit, without disclosing the contamination that resulted from the process change.

The Master Complaints layout similar facts for each Manufacturer Defendant, including combination API/finished dose manufacturers Mylan (*see, e.g.*, PIMC ¶¶ 301-331; ELMC ¶¶ 267-297, MMMC ¶¶ 219-249), Aurobindo (*see, e.g.*, PIMC ¶¶ 286-300; ELMC ¶¶ 252-266; MMMC ¶¶ 250-265), and Hetero (*see* PIMC ¶¶ 332-345; ELMC ¶¶ 298-311; MMMC ¶¶ 205-218), as well as for finished-dose only manufactures Teva (*see, e.g.*, PIMC ¶¶ 41, 42, 284, 285; ELMC ¶¶ 250-251; MMMC ¶¶ 203-204), Torrent (*see, e.g.*, PIMC ¶¶ 284, 285; ELMC ¶¶ 250-251; MMMC ¶¶ 203-204) and Camber (*see, e.g.*, PIMC ¶177; ELMC ¶¶ 59-61, 383-384; MMMC ¶¶ 31, 33, 340-341).

Thus, far from "failing to allege any factual basis for their fraud claims," *see* Mfr. Br. at 25, the Master Complaints' allegations are more than sufficient to apprise Manufacturer Defendants of the who, what, when, where, and why pleading requirement of Rule 9(b).

Manufacturer Defendants' assertion that no individual allegation sufficiently alleges each

defendant's scienter (*see id.* at 36-38) overstates Plaintiffs' obligation at the pleading stage. Plaintiffs need not plead an irrefutable fact of scienter "of the 'smoking gun' genre." *Institutional Investors Grp. v. Avaya, Inc.*, 564 F.3d 242, 267 (3d Cir. 2009). Rather, Rule 9(b) expressly provides that "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). "Pleading circumstantial grounds for such knowledge" is sufficient to meet the Rule 9(b) standard." *Caspersen ex rel. Samuel M.W. Caspersen Dynasty Trust v. Oring*, 441 F. Supp. 3d 23, 40 (D.N.J. 2020) (McNulty, J.). Thus, "[t]he pertinent question is whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Id.* (internal quotations and citation omitted).

The Master Complaints' allegations, taken as a whole, certainly satisfy this standard. As discussed *supra*, each Manufacturer Defendant's manufacturing practices so departed from the standards of care, which "present[ed] a danger of misleading buyers or sellers" that a plausible inference may be drawn that they knew of the risks created by their contaminated valsartan API and finished dose, or that such risks were "so obvious that the actor must have been aware of it." *Id.* (internal quotations and citation omitted). In recently refusing to dismiss claims in the talcum powder litigation Judge Wolfson found:

> Plaintiff has sufficiently pled that, at minimum, those defendants had access to information which would have alerted them to the allegedly misleading nature of their statements regarding the safety of the products. As alleged, Defendants either failed to adequately investigate the potential dangers of the Talc Products, despite its obvious relevance evidenced by the many public inquiries, or Defendants knowingly disseminated false and inaccurate statements as part of a long standing fraudulent scheme. Either scenario is suggestive of scienter.

Hall v. Johnson & Johnson, No. 18-1833, 2019 WL 7207491, at *25 (D.N.J. Dec. 27, 2019). That the Master Complaints allege what each Manufacturer Defendant knew, or should have known, is

sufficient to preclude dismissal under Rule 12 (b)(6).[43]

Manufacturer Defendants' charts, suggesting that some states' laws require actual knowledge of the fraud, or alternatively reckless indifference, *see* ECF 520-5 at 16-22, do not move the needle. Whether or not a particular state's law ultimately requires evidence that a defendant actually knew of the underlying fraud, or was recklessly indifferent to it, will be answered by reference to facts to be developed during discovery. For Rule 12 purposes, it suffices that the Master Complaints plausibly plead facts suggesting each Defendant knew or should have known of the contamination and either affirmatively misrepresented or omitted that fact.

c. Wholesaler Defendants

Wholesalers' lack of privity with consumers does not preclude Plaintiffs' fraud claims against them as a matter of law. To the contrary, a wholesale distributor that sells to retailers, but not consumers, may still be liable in tort for its fraud and other violations of common law duties. *See, e.g.*, *Ebin v. Kangadis Family Mgmt LLC*, 45 S. Supp. 3d 395, 398-401 (S.D.N.Y. 2014) (certifying nationwide class of consumers who purchased allegedly mislabeled olive oil that had been distributed by defendant, even though defendant did not sell directly to consumers); *In re Takata Airbags Prods. Liab. Litig.*, No. 15-02599-MD, 2020 WL 2892366 (S.D. Fla. June 1, 2020) (refusing to dismiss consumer class claims against distributor of vehicles with purportedly defective airbags under fraud and other theories).

Wholesaler Defendants concoct their own insurmountably high bar in arguing that the Master Complaints do not adequately allege what each of them knew, and do not itemize each alleged fraudulent statement or omission. Both arguments miss the mark. Even under Rule 9(b),

[43] Manufacturer Defendants are incorrect that what each of them "should have known" is immaterial. *See* Mfr. Br. at 35-36. To the contrary, states' laws specifically contemplate that a fraud claim may lie if a defendant knew or should have known through reasonable inquiry of an omission or defect. *See supra*.

a plaintiff need not (and usually cannot) plead a defendant's state of mind with specificity. *See, e.g.*, *State Capital Title & Abstract Co. v. Pappas Bus. Servs., LLC*, 646 F. Supp. 2d 668, 682 (D.N.J. 2009) (Wolfson, J.) ("a plaintiff need only plead generally with respect to the defendant's state of mind"). Moreover, a plaintiff need not inevitably plead the "date, place or time" of every fraudulent utterance, so long as they use alternative means of injecting precision and some measure of substantiation into a fraud allegation. *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007).

Plaintiffs have done this. Here, the Master Complaints allege that each Wholesaler Defendants "failed to take any steps to test or otherwise confirm the purity or bioequivalence of the contaminated, adulterated and/or misbranded VCDs." ELMC ¶ 113; MMMC ¶¶ 118-120. Each Wholesaler Defendant was obliged to quarantine or investigate potentially illegitimate (including adulterated and/or misbranded) drugs. ELMC ¶ 113; MMMC ¶¶ 118-120. "Wholesaler Defendants knew or should have known, based on information provided or available from each manufacturer defendant, of the actual or potential adulteration, misbranding, or contamination of VCDs they purchased from manufacturer defendants. Wholesaler Defendants expressly or impliedly warranted VCDs they sold were not adulterated, misbranded, or contaminated, when in fact that was not the case." ELMC ¶ 113; MMMC ¶¶ 118-120. Each Wholesaler Defendant sold VCDs by representing them as therapeutically equivalent or the same as valsartan, and complied with cGMPs. *See* ELMC ¶ 493; MMMC ¶¶ 118-120. Wholesaler Defendants omitted the material fact that their VCDs were not therapeutically equivalent to their RLDs and did not comply with cGMPs and/or were adulterated, misbranded, and/or unapproved. *See* ELMC ¶ 494; MMMC ¶¶ 118-120.

Further, it must be remembered that Wholesaler Defendants' fraud was a repetitive series of acts, not an isolated instance. No purpose is served by requiring a painstaking list of the date,

place, and time of each fraudulent statement that accompanied each sale of VCDs by Wholesaler Defendants. The answer, as alleged, is the same: each VCD sold by Wholesaler Defendants was not what it purported to be.

Additionally, the Master Complaints allege fraud by omission, not just affirmative misrepresentations. *See, e.g.,* ELMC ¶ 113; MMMC ¶¶ 118-120; PIMC ¶¶ 168-174. Each Defendant here was under a duty to comply with federal and parallel state requirements about the contents of their VCDs, such that what they sold matched the FDA-approved labeling. Every sale of VCDs by Wholesaler Defendants that went unaccompanied with a disclosure of contamination – which was all sales – was actionable fraud by omission.

d. Retail Pharmacy Defendants

Retailers who sell fraudulently mislabeled products to consumers may be liable for their own actions or inactions. *See, e.g.*, *Dzielak v. Whirlpool Corp.*, 26 F. Supp. 3d 304 (D.N.J. 2014) (McNulty, J.) (refusing to dismiss, inter alia, consumer protection claims against manufacturer and retailers from whom consumers purchased washing machines). As with Wholesaler Defendants, each Retail Pharmacy Defendant sold VCDs by representing them as therapeutically equivalent or the same as valsartan, and complied with cGMPs. *See, e.g.*, ELMC ¶ 493; MMMC ¶¶ 296-305. Each omitted the material fact that their VCDs were not therapeutically equivalent to their RLDs and did not comply with cGMPs and/or were adulterated, misbranded, and/or unapproved. *See, e.g.*, ELMC ¶ 494; MMMC ¶¶ 296-305; *see, e.g.*, *In re Propulsid Prods. Liab. Litig.*, MDL No. 1355, 2001 WL 1446714, at *2 (E.D. La. July 2, 2002) (denying motion to dismiss fraudulent and negligent misrepresentation claims against pharmacies).

6. The PIMC Adequately Pleads Products Liability – Failure to Warn Claims

"A duty to warn arises if [Defendant] (the manufacturer/seller) actually *knew or should have known* of the need to issue a particular warning." N.J. Model Civil Jury Charges 5.40C; *In re Accutane Litigation*, 194 A.3d 503, 530 (N.J. 2018); *see also Suchomajcz v. Hummel Chem. Co.*, 524 F.2d 19, 25 (3d Cir. 1975). The PIMC adequately alleges that Defendants knew or should have known of (1) the nitrosamine contamination of their valsartan, and (2) the dangers of those nitrosamines. *See, e.g.*, PIMC ¶¶ 148-155, 157-164, 168, 189-99, 215, 266-345.

Defendants frame the issue as if they have forgotten that their valsartan was recalled throughout the world due to the nitrosamine contamination. PIMC ¶¶ 170-86. Assuming the truth of these allegations and all their favorable inferences, Plaintiffs have adequately pleaded that Defendants knew or should have known that their nitrosamine-contaminated Valsartan could cause cancer in humans, and failed to warn of these risks.

Discovery has yielded illustrative evidence on this point. *See* ECF 296 at 4-7. As the PIMC alleges, Defendants' cGMP and quality assurance violations caused them to either willfully ignore these peaks or fail to detect them. Similar failures are alleged as to all of the relevant Defendants.

This Court should deny Defendants' motion to dismiss the PIMC's failure-to-warn claims.

7. The PIMC Adequately Pleads Products Liability – Design Defect Claims

The Manufacturing Defendants assert that PIMC's design defect allegations are "conclusory." The gravamen of Defendants' attack is that the PIMC pleads facts related to deficiencies in Defendants' manufacturing practices as opposed to the design of VCDs. However, they ignore wide swaths of allegations and Plaintiffs' alternative theories. In particular, the PIMC pleads two alternate frameworks for assessing the Manufacturing Defendants' liability: a manufacturing defect of an existing design for VCD and a defect in the design of a wholly new—

and unapproved—VCD. As the alleged facts support either theory, Defendants' request for dismissal must be rejected.

As a preliminary matter, it is well established that plaintiffs are the master of their complaint. *See, e.g., Holmes Grp., Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826, 831 (2002). And Plaintiffs may allege alternative and conflicting theories of liability. *Gov't Guarantee Fund v. Hyatt Corp.*, 166 F.R.D. 321, 324 (D.V.I.), *aff'd sub nom.*, *Gov't Guarantee Fund of Republic of Finland v. Hyatt Corp.*, 95 F.3d 291 (3d Cir. 1996); *see also* Fed. R. Civ. P. 8 (A party may state as many separate claims or defenses as it has, regardless of consistency). And that is precisely what Plaintiffs have done here.

Contrary to Manufacturer Defendants' contention, the PIMC alleges facts interpretable as either a manufacturing or design defect. The latter framework is directly explained in the PIMC:

> FDA further requires that whenever a new, active ingredient is added to a drug, then the drug becomes an entirely new drug, necessitating a submission of a New Drug Application by the manufacturer. Absent such an application, followed by a review and approval by the FDA, this new drug remains a distinct, unapproved product.

PIMC ¶ 216. It continues:

> [W]hen a generic manufacturer ceases to manufacture a drug that meets all terms of its approval, or in other words, when the drug is not the same as its corresponding brand-name drug, then the manufacturer has created an entirely new (and unapproved) drug.

PIMC ¶ 218. Thus, rather than following the FDA-approved design for VCDs, Manufacturing Defendants chose to bring new designs to market that contained nitrosamines such as NDMA and NDEA. *See* PIMC ¶¶ 213-216, 451-453. And the presence of those cancer-causing nitrosamines is the defect in those new and unapproved drugs.

The PIMC fills out this framework with allegations covering the other elements of design defect. For instance, it explains how the newly designed VCDs were unsafe for intended use. *See*

PIMC ¶¶ 145-164 (discussing harms associated NDMA, NDEA, and other contaminants), ¶ 178 (VCDs contained up to 177 times safe level of NDMA). And it describes how the dangers associated with nitrosamines were known and foreseeable. *Id*.; *see also* i ¶¶ 414-415. And, Plaintiffs identified a readily apparent and existent reasonable alternative design: the non-nitrosamine VCD design approved by the FDA. *See* PIMC ¶ 456 (identifying FDA approved design that did not include nitrosamines as a reasonable alternative design). Plaintiffs' design defect claim is also consistent with the allegations that the Manufacturing Defendants knew their products contained the damaging impurities. *See, e.g.*¸ PIMC ¶¶ 196-200 (ZHP aware of presence of impurities and intentionally hid them), ¶¶ 317-322 (Mylan manipulated testing); *see also* PIMC ¶ 168 (pharmaceutical industry aware of potential for formation of nitrosamines since 2005), ¶¶ 414-415 (Defendants knew or had reason to know).

In sum, the facts alleged in the PIMC plausibly suggest two possible defect theories: (1) dangerous nitrosamines were introduced into Defendants VCDs due to poor manufacturing practices and (2) Defendants created new VCD designs that included nitrosamines in order to better compete in the market—for instance by being cheaper to manufacturer than other VCD designs. Though facts established in discovery may eventually eliminate one of these theories, dismissal would be inappropriate at this early stage. *See Anderson News, L.L.C. v. Am. Media, Inc.*, 680 F.3d 162, 185 (2d Cir. 2012) ("choice between two plausible inferences that may be drawn from factual allegations is not a choice to be made by the court on a Rule 12(b)(6) motion"). Accordingly, the Court should deny Defendants' motion in this respect.

8. The PIMC Properly Pleads Claims for Wrongful Death, Survival, and Loss of Consortium, as well as Its Demand for Punitive Damages

a. This Court should not dismiss the PIMC's derivative claims

The PIMC's wrongful death, survival, and loss of consortium claims are derivative of the other claims. *See., e.g.*, *Giardina v. Bennett*, 545 A.2d 139, 145 (N.J. 1988) (wrongful death); *Smith v. Whitaker*, 734 A.2d 243, 249 (N.J. 1999) (survival); *Ryan v. Renny*, 999 A.2d 427, 443 n.1 (N.J. 2010) (loss of consortium); *see also Marie v. McGreevey*, 314 F.3d 136, 140 (3d Cir. 2003) (wrongful death); *Gomez v. H&M Int'l Transp., Inc.*, No. 17-231, 2017 WL 1483306, at *4 (D.N.J. Apr. 24, 2017) (Linares, J.) (survival); *Petrocelli v. Daniel Woodhead Co.*, 996 F.2d 27, 30 (3d Cir. 1993) (loss of consortium). Thus, the Court should deny Defendants' motion to dismiss the PIMC's wrongful death, survival, and loss of consortium claims for the same reasons that it should deny Defendants requests to dismiss the PIMC's other causes of action.

b. This Court should not dismiss the PIMC's request for punitive damages

Courts "should not decide the availability or unavailability of punitive damages as a matter of law on a motion to dismiss." *Jones v. Francis*, No. 13–04562, 2013 WL 5603848, at *3 (D.N.J. Oct. 11, 2013) (Chesler, J.)

> As demonstrated in the standard of review section that accompanies this and every other opinion on a Rule 12(b)(6) motion, **the "plausibility" pleading regime addresses the types of facts a plaintiff must allege to make out a cause of action, not the types of damages the alleged cause of action may eventually warrant.** Indeed, nothing in *Twombly*, *Iqbal*, or their progeny refers to pleading requirements for damages requests at all; instead, the cases themselves analyze the well-pleaded facts exclusively in the context of the elements of the alleged cause of action. *See* [*Ashcroft v.*] *Iqbal*, 556 U.S. [662] 680, 687 [(2009)] ("Rule 8 does not empower respondent to plead the bare elements of his cause of action [for invidious discrimination] . . . and expect his complaint to survive a motion to dismiss."); *see also Malleus v. George*, 641 F.3d 560, 563 (3d Cir. 2011) ("a court must . . . look[ ] at the well-pleaded

> components of the complaint and evaluat[e] whether all of the elements [a plaintiff must plead to state a claim] are sufficiently alleged"). **In sum, once a civil complaint shows a claim to be "facially plausible,"** *Fowler* [*v. UPMC Shadyside*], 578 F.3d [203,] 210 [(3d Cir. 2009)], **nothing in Rule 8 or its judicial gloss suggests, let alone requires, that this Court scrutinize the damages requested by plaintiff as redress for that claim.**
>
> * * *
>
> **Were the Court to accept Defendants' argument, every request for damages, including standard fare like attorneys' fees or "such other relief as the Court may deem proper," . . . , could be attacked at the motion to dismiss stage, on the theory that the facts alleged did not support a claim for such a remedy.** Requests for this type of relief, while boilerplate, embody a central tenet of notice pleading under the federal rules, even post *Twombly* and *Iqbal*—**once a plaintiff plausibly states his cause of action, subsequent discovery may reveal facts that bring to light previously unknown but nevertheless appropriate redress.**

Id. at *2, 3 n.3; *see also Duell v. Kawasaki Motors Corp.*, No. 12-7273, 2014 WL 12908947, at *2 (D.N.J. July 18, 2014) (Donio, M.J.). Therefore, this Court should decline to analyze the adequacy of the allegations underlying the PIMC's request for punitive damages.

As a substantive matter, the PIMC adequately alleges punitive damages. In New Jersey,[44] punitive damages are available when "the harm suffered was the result of the defendant's acts or omissions, and such acts or omissions were actuated by *actual malice or accompanied by a wanton and willful disregard* of persons who foreseeably might be harmed by those acts or omissions." N.J.S.A. 2A:15-5.12(a) (emphasis added). *See Gremo v. Bayer Corp.*, 2020 WL 3496917, at *12

[44] Plaintiffs note that Defendants attached a seven-page chart to their brief allegedly summarizing each state's law on punitive damages. However, that chart does not contain a single citation in support of its summary. To the extent that Defendants supply authority from other states in their brief, those states only require gross negligence to underpin punitive damages. The PIMC adequately alleges Defendants engaged in a higher level of misconduct—namely, willful and wanton misconduct.

(D.N.J., June 29, 2020) (Hillman, J.) (denying motion to dismiss punitive damages claim under NJPLA).

The PIMC adequately alleges that Defendants engaged in this level of misconduct. "[I]f Defendants had not routinely disregarded the FDA's cGMPs, including those discussed throughout this Complaint and the FDA's investigation reports and warning letter, and deliberately manipulated and disregarded sampling data suggestive of impurities, or had fulfilled their quality assurance obligations, Defendants would have identified the presence of these nitrosamine contaminants almost immediately." PIMC ¶188. In fact, Defendants continued to violate cGMPs and quality assurance standards even after the FDA notified them of their violations of those rules, and many Defendants used upstream Defendants as suppliers in spite of being on notice of those dangerous violations and their propensity to lead to the contamination of their VCDs with carcinogenic nitrosamines. *See, e.g.*, PIMC ¶¶ 189-99, 266-345.

Defendants put profits ahead of safety, and effectively ignored cGMPs and quality assurance rules in order to save money producing their Valsartan and increase their profits in the process. For example, in its Warning Letter to ZHP, the FDA wrote:

> In November 2011 you approved a valsartan API process change (PCRC - 11025) that included the use of the solvent DMF. **Your intention was to improve the manufacturing process, increase product yield, and lower production costs. However, you failed to adequately assess the potential formation of mutagenic impurities when you implemented the new process.** Specifically, you did not consider the potential for mutagenic or other toxic impurities to form from DMF degradants, including the primary DMF degradant, dimethylamine. According to your ongoing investigation, dimethylamine is required for the probable human carcinogen NDMA to form during the valsartan API manufacturing process. NDMA was identified in valsartan API manufactured at your facility.

PIMC ¶ 280 (emphasis added). When asked why it made this change, ZHP's Executive Vice President Jun Du suggested it was to save money increase market share. *See* ECF 296 at 4-5.

Even more egregiously, ZHP instituted this manufacturing change at a commercial scale in spite of its developer's direction that the synthesis and purification process including the solvent system had to be further refined at the testing scale. *Id.* These facts lead to one reasonable conclusion: ZHP wantonly and willfully manufactured its valsartan using an unoptimized purification process that failed to detect highly potent genotoxic impurities, such as NDMA or NDEA, so that it could increase its profits and market share.

ZHP's violations were not unique in this case. *See, e.g.*, PIMC ¶¶ 189-99, 266-345. Defendants were all competitors, and they all willfully and wantonly failed to detect the carcinogenic nitrosamines in their valsartan in order to increase their profits and market shares. *Id.* These nitrosamines then caused Plaintiffs to develop cancer. PIMC ¶¶ 148-155, 157-164, 170-86, 215. Given these allegations and all their favorable inferences, this Court should deny Defendants' motion to dismiss the PIMC's request for punitive damages. N.J.S.A. 2A:15-5.12(a).

9. The MMMC Adequately Pleads Medical Monitoring Claims

In seeking to dismiss certain of the medical monitoring claims, Defendants dramatically overstate purported differences in the laws, and even falsely assert that medical monitoring is not available in 20 states. ECF 520-3 at 53. This is incorrect. As a threshold matter, medical monitoring is a common remedy, and even if New Jersey law did not apply nationwide (which will be determined), there are a large cluster of states where courts have explicitly recognized medical monitoring as a substantive claim with remedies, and other states, whether or not medical monitoring is an independent claim, where it is a well-settled remedy under facts such as those alleged in this case. Unsurprisingly there are minor differences in language, but not one of the 20 states Defendants identify as those where medical monitoring is unavailable has in fact rejected

the availability and propriety of medical monitoring remedies in appropriate cases.[45] *See* Pls.' Appx.[46]

Defendants' attacks on the law in specific states (including those where Defendants otherwise acknowledge that medical monitoring is viable) are likewise misplaced. Thus, Defendants misstate the law of many states listed in the charts they have compiled and attached to accompany their motion. *See* ECF No. at 520-5 at pp.57-60. By way of example, Defendants list Indiana as one of the states that does not recognize medical monitoring as an independent cause of action. *Id.* at p.57 (citing *Hunt v. Am. Wood Preservers Inst*., No. IP 02-0389, 2002 WL 34447541, at *1 (S.D. Ind. July 31, 2002)). But, to the contrary, more recently the District Court for the Southern District of Indiana has indicated "Indiana law ***would*** probably recognize . . . a claim for medical monitoring damages" under proper circumstances. *In Allgood v. GMC*, No. 1:02-cv-1077-DFH-TAB, 2006 U.S. Dist. LEXIS 70764, at *7 (S.D. Ind. Sep. 18, 2006) (emphasis added) (relying on *Gray v. Westinghouse Electric Corp*., 624 N.E.2d 49 (Ind. App. 1993)).

For the Court's reference, Plaintiffs attach their own Chart showcasing a state-by-state representation of medical monitoring laws and the relevant authority for each state. *See* Pls.' App. Plaintiffs submit they have sufficiently stated claims for medical monitoring damages in the states that recognize medical monitoring as an intendent cause of action. In states where medical monitoring is less clearly defined as a cause of action or requires a showing of injury, Plaintiffs submit they have pled other predicate claims upon which medical monitoring is an appropriate and recognized remedy.

---

[45] At most, certain states have not clearly addressed the issue of medical monitoring or articulated a clear test to date, which in no way supports Defendants' drastic and unsupported argument. *See* Pls.' Appx.

[46] *See also* NOTE AND COMMENT: A FIFTY-STATE SURVEY OF MEDICAL MONITORING AND THE APPROACH THE MINNESOTA SUPREME COURT SHOULD TAKE WHEN CONFRONTED WITH THE ISSUE, 32 Wm. Mitchell L. Rev. 1095, 1114 (2006).

To the extent Defendants are arguing to dismiss Plaintiffs' claims on the basis of purported differences in state law, this argument should also be rejected because it is a premature and misplaced attack on class certification. In another case regarding an allegedly toxic chemical, a district court recently denied defendants' motion to dismiss a nationwide class action in which medical monitoring was sought. *See e.g., Hardwick v. 3M Co*., No. 2:18-cv-1185, 2019 U.S. Dist. LEXIS 169322 (S.D. Ohio Sep. 30, 2019). There, the court rejected defendants' argument that, "medical monitoring around the country in various jurisdictions has taken on a variety of forms." *Id*. at *29. Instead, the court held that it "need not make a determination as to the exact nature of the requested relief as long as it has the power to provide some of the requested relief, which is the case as to medical monitoring . . . ." *Id.* at *30. The same result should follow here.

E. Pharmacies May Be Subject to Strict Liability Without Fault

The Retail Pharmacy Defendants would have this Court believe that every state in the nation has found that pharmacies are immune from strict liability. This is simply incorrect. In the context of product liability, a number of states have adopted the strict liability framework articulated in section 402A by the Restatement (Second) of Torts, which broadly defines a "manufacturer" of a product to include "any manufacturer of a product, to any wholesale or retail dealer or distributor." *See, e.g., Promaulayko v. Johns Manville Sales Corp.*, 562 A.2d 202, 205 (N.J. 1989); *Livingston v. Begay*, 652 P.2d 734, 737-38 (N.M. 1982); *Peterson v. Lou Bachrodt Chevrolet Co.*, 329 N.E.2d 785, 786 (Ill. 1975); *Seattle-First Nat. Bank v. Volkswagen of Am., Inc.*, 525 P.2d 286, 289 (Wash. 1974); *Ritter v. Narragansett Elec. Co*., 283 A.2d 255, 261 (R.I. 1971); *Dippel v. Sciano*, 155 N.W.2d 55, 63 (Wis. 1967). "Support of this rule is widespread," and under this standard, "any seller in the chain of distribution is liable for the sale of a defective product that was a cause of the plaintiff's injury." Restatement (3d) of Torts: Prod. Liab. § 1 (1998).

The Retail Pharmacy Defendants claim they are not subject to these state's strict liability laws because they are not "sellers" but rather "perform a service of dispensing a product" that places them beyond the scope of strict liability. *See* Retail Pharmacy Br. at 18. Courts have disagreed with this contention, focusing on the "principle" function of the pharmacy, which is "the sale of medication"—as noted by one court:

> In this case, the plaintiff went to the pharmacy to purchase a prescription drug and nothing more. Although the filling of a prescription may involve some service, such as checking for conflicts in medication, it seems clear that the plaintiff primarily expected to receive Requip, a drug prescribed by his doctor. This court finds that the defendant pharmacy is a "product seller" under the CPLA, because *the principal part of the transaction was the sale of medication*.

Stanko v. Bader, No. CV-03-0193669, 2003 WL 22413476, at *3 (Conn. Super. Ct. Oct. 7, 2003) (emphasis added); *Kohl v. Am. Home Prod. Corp.*, 78 F. Supp. 2d 885, 895 (W.D. Ark. 1999) ("While the manufacturer defendants devote much of their argument to the contention that the pharmacy defendants cannot be held strictly liable because they provide a service rather than a product, we find this distinction rather shaky in the pharmacy context."). The Retail Pharmacy Defendants quote *Murphy v. E. R. Squibb & Sons, Inc.*, 40 Cal. 3d 672 (Cal. 1985), for certain public policy reasons as to why pharmacies should be considered service providers. But the *Murphy* court found that pharmacies would be subject to strict product liability had the California legislature not passed separate legislation exempting pharmacies and suppliers of blood. *Id.* at 679-680. Recognizing that a pharmacy "is engaged in a hybrid enterprise" of sales and service, the *Murphy* court found "selling" to be the predominant function of the pharmacy:

> The pharmacist is in the business of selling prescription drugs, and his role begins and ends with the sale. His services are rendered only in connection with the sale, and a patient who goes to a pharmacy to have a prescription filled generally is seeking to purchase the drug rather than to obtain the advice of the pharmacist.

> By contrast, the doctor, dentist and hospital in the cases cited above are not in the business of selling the drug or device; they use the product in the course of treatment as one element in their efforts to effect a cure, and furnishing the services does not depend on sale of a product.

Id. at 251–52. Thus, when a pharmacy engages in the act of "selling" a drug, such as alleged in the PIMC, it is a "seller within the chain of distribution" and subject to strict liability. *See* Restatement (2d) of Torts: Prod. Liab. § 402A, cmt. f.

The Retail Pharmacy Defendants also misstate the primary "policy objectives" of strict liability statutes. *See* Retail Pharmacy Br. at 19. "The purpose of strict liability is to insure that the cost of injuries resulting from defective products are borne by the manufacturers (and sellers) that put such products on the market rather than by the injured persons who are powerless to protect themselves." *Greenman v. Yuba Power Prod., Inc.*, 377 P.2d 897, 901 (Cal. 1963); *see also Potter v. Chicago Pneumatic Tool Co.*, 694 A.2d 1319, 1328 (Conn. 1997); *Swenson Trucking & Excavating, Inc. v. Truckweld Equip. Co.*, 604 P.2d 1113, 1116 (Alaska 1980); *Keener v. Dayton Elec. Mfg. Co.*, 445 S.W.2d 362, 364 (Mo. 1969). While strict liability statutes may result in additional measures by downstream distributors and sellers to ensure the safety of products, "[t]he policy considerations underlying strict liability is to insure, except for misuse and assumption of risk, a consumer's full recovery." *Frazer v. A.F. Munsterman, Inc.*, 527 N.E.2d 1248, 1257 (Ill. 1988). The Retail Pharmacy Defendants, as sellers of drug products, are well within the scope of the policy reasons for strict liability. To the extent that such liability is considered "derivative" or secondary liability, individual states provide measures of recourse, such as indemnification and contribution, that serve to minimize potential inequity while still protecting the injured person. *See, e.g., Bylsma v. R.C. Willey*, 416 P.3d 595, 607–08 (Utah 2017) ("[W]hereas the purpose of products liability generally is to shift the burden of loss from an injured party to the sellers of a defective product as a collective whole, the purpose of implied indemnity is to shift the burden

from an individual passive retailer—who bears no fault in the usual sense of the word—onto the party responsible for the defect, the manufacturer.")*; Promaulayko v. Johns Manville Sales Corp.*, 562 A.2d 202, 205 (N.J. 1989) ("In the absence of an express agreement between them, allocation of the risk of loss between the parties in the chain of distribution is achieved through common-law indemnity, an equitable doctrine that allows a court to shift the cost from one tortfeaser to another."); *Piedmont Equip. Co., Inc. v. Eberhard Mfg. Co.*, 665 P.2d 256, 259 (Nev. 1983) (finding that manufacturer must indemnify distributor in strict liability action); *Frazer*, 527 N.E.2d at 1257 ("[I]n strict liability actions the principle of comparative fault is applicable to joint tortfeasors."); *Smith Radio Commc'ns, Inc. v. Challenger Equip., Ltd.*, 527 P.2d 711 (Or. 1974) (holding that a secondarily liable retailer that does not themselves cause any defect in the goods may seek indemnification from the manufacturer).

As much as the Retail Pharmacy Defendants wish to depict the law as being uniform in absolving them from liability, the reality is far from that. Many states have not addressed this issue at all, such as Alaska, Hawaii, Maine, New Hampshire, and South Dakota. In those that have, any restriction on strict liability has been generally limited to claims of failure to warn—not manufacturing or design defect.[47] Furthermore, while some states have enacted statutes limiting strict liability as to innocent sellers, the PIMC alleges, as explained above, that Pharmacy Defendants knew or should have known of the defect and yet did nothing; moreover, most innocent seller statutes contain exceptions permitting liability to attach such as where the manufacturer of the product cannot be identified, there are jurisdictional issues, or potential insolvency of other

[47] *See, e.g., Ramos v. Rite Aid Corp.*, No. CV106008649, 2010 WL 4277612, at *1 (Conn. Super. Ct. Oct. 7, 2010).

defendants.[48] These exceptions cannot be determined inapplicable in absence of full discovery; for example the assets of the manufacturers must be investigated as substantive discovery. *See, e.g.*, *Thomas v. Firerock Prods., LLC*, 40 F. Supp. 3d 783, 792(N.D. Miss. 2014) (denying motion to dismiss on basis of innocent seller affirmative defense because elements not obviously met on face of complaint); *Fahy v. Taser Int'l, Inc.*, No. 4:10-cv-19, 2010 WL 559249, at *2 (E.D. Mo. Feb. 10, 2020) (Missouri's innocent seller statute "does not affect a defendant's potential liability to a plaintiff at the pleadings stage"); *Geraczynski*, 2013 WL 5934552, at *4 (only ruling on innocent seller defense at summary judgment after discovery.

Indeed, to ascertain the contours and exceptions of the product liability laws of every jurisdiction potentially involved in this litigation requires an in-depth analysis that is not accomplished in the chart put forth by the Pharmacy Defendants. Not only is the chart incomplete and inaccurate in many respects,[49] but the chart does not (nor could it) address individual personal injury plaintiffs' circumstances that could impact the liability of the Pharmacy Defendants. For instance, the Pharmacy Defendants do not address the choice of law issues applicable to personal injury plaintiffs that filled prescriptions in multiple states, used a mail-order pharmacy service, or received treatment in a state different than where they filled their prescription. Such issues must

[48] *See, e.g.,* Ala. Code § 6–5–521(c); *see also, e.g.,* D.C.A. tit. 18 §7001 (Delaware); Ind. Code § 34-20-2-4; Iowa Code § 613.18; KSA 60-3306 (Kansas); KRS 411.340 (Kentucky); Md. Code Ann., Cts. & Jud. Proc. § 5-405; Minn. Stat. § 544.41 (Minnesota); Mo. Ann. Stat. § 537.762 (Missouri); N.J. Stat. § 2A:58C-2 (New Jersey); N.C.G.S.A. § 99B-2(a) (North Carolina); N.D. Cent. Code § 28-01.3-04 (North Dakota); O.R.C. 2307.78(B) (Ohio); Okla. Stat. tit. 76, § 52.2.E (Oklahoma); Tenn. Code Ann. §29-28-106 (Tennessee); Texas CPRC Sec. 82.003(a)(7); Wis. Stat. § 895.047 (Wisconsin).

[49] For instance, the Retail Pharmacy Defendants claim in the chart that "[r]egardless of legal theory, no claims against pharmacy," but the law they cite is limited to failure to warn claims—not manufacturing and design defect claims—and there are exceptions to the innocent seller rule. Similar errors exist for other states, such as Alaska, Connecticut, the District of Columbia, Florida, Illinois, Maryland, Massachusetts, Montana, Utah, and Wyoming.

be addressed on a case-by-case basis that is inappropriate in the context of a master complaint. Rather, motions to dismiss implicating the facts of personal injury plaintiffs are premature and are more appropriately assessed during the bellwether trial process or upon remand. Accordingly, given the lack of uniformity in the application of strict liability to pharmacies and the impracticality of resolving individual personal injury plaintiff issues in the context of a master complaint, the Pharmacy Defendants' Motion should be denied in this respect.

F. The Three "FDA Liaison" Defendants' Fact-Intensive Arguments For Dismissal Are Premature

The so-called "FDA Liaison Defendants" – Prinston, Aurobindo USA, and Hetero USA – argue they should be dismissed because they claim (i) the Complaints are "devoid of any allegations" against them, and (ii) they are mere intermediaries between their Manufacturer Defendant affiliates and the FDA. *See* Mfr. Br. at 57-59. Neither argument is a proper basis for dismissal.

Prinston, Aurobindo USA, and Hetero USA's assertion that they had nothing to do with the manufacture, distribution and sale of VCDs is not only belied by the allegations and reality, but it is a fact question not suspectible to a motion to dismiss. The Master Complaints plead specific allegations as to each of these three defendants. For instance, Prinston also does business at Solco. *See* ELMC ¶ 51; MMMC ¶ 23; PIMC ¶¶ 37-38. Prinston listed its own valsartan for sale on its website, *see, e.g.*, ELMC ¶ 378; MMMC ¶ 335; PIMC ¶ 358, multiple repackagers announced recalls of VCDs they claimed to have sourced from Prinston, *see* ELMC ¶¶ 113, 119; MMMC ¶¶ 97, 99; PIMC ¶ 36, and the FDA's own ARB recall website identifies several VCDs as being sold by Prinston that had high NDMA contamination levels, ELMC ¶ 250; MMMC ¶ 203; PIMC ¶¶ 58, 60, 284. Likewise, Aurobindo USA boasts on its own website that it "adds value through superior customer service in the distribution of a broad line of generic pharmaceuticals, leveraging vertical integration and efficient controlled processes." ELMC ¶ 72 & n.11; MMMC ¶

44; PIMC ¶¶ 372-376. The FDA identified multiple recalled VCDs as being traced back to Aurobindo USA. *See* ELMC ¶ 257 n.52; MMMC ¶ ¶ 259, 265; PIMC ¶ 300. And Hetero USA is no mere intermediary, but rather has self-identified as "US representation of HETERO," *see* ELMC ¶ 358; MMMC ¶ 30; PIMC ¶ 63. Hetero USA is also identified on the FDA ARB recall website as responsible for multiple VCDs being recalled due to high contamination levels. *See* ELMC ¶ 302 n.73; MMMC ¶ 218; PIMC ¶ 177.

These alleged facts are more than sufficient to defeat Rule 12(b) dismissal. Indeed, the sole case cited by Defendants was decided at summary judgment after the development of a factual record. *See Moore v. Medeva Pharms., Inc.*, No. 01-311-M, 2004 WL 57084, at *4 (D.N.H. Jan. 13, 2004). As in *Moore*, any decision to dismiss the "FDA Liaison" Defendants should be deferred until Summary Judgement.

G. Retail Pharmacy and Wholesaler Defendants' Innocent Seller Defense Does Not Require Dismissal of Any Count

The Retail Pharmacy and Wholesaler Defendants claim that the innocent seller statutes available in certain states should relieve them of liability in this litigation. Aside from the fact that this affirmative defense only potentially relates to products liability claims, Defendants fail to mention that the majority, if not all, of these statues provide exceptions that may be applicable here and are not identified in the chart they provided, which is inaccurate and incomplete in many respects. For instance, the innocent seller statute in Alabama provides that "if a claimant is unable, despite a good faith exercise of due diligence, to identify the manufacturer of an allegedly defective and unreasonably dangerous product, a product liability action may be brought against a distributor, wholesaler, dealer, retailer, or seller of a product." Ala. Code § 6–5–521(c); *see also, e.g.,* D.C.A. tit. 18 §7001 (Delaware); Md. Code Ann., Cts. & Jud. Proc. § 5-405.

Referred to as "Product ID," this is a common issue in pharmaceutical litigation due to difficulties in tracing the precise manufacturer of a drug where there exist multiple manufacturers

for the same drug. In some states, like Illinois, the innocent seller statute requires that the nonmanufacturer defendant "file an affidavit identifying the manufacturer of the product in question and the manufacturer is joined in the suit." *Breeze v. Bayco Prod. Inc.*, No. 3:19-CV-00848-NJR, 2020 WL 4365471, at *2 (S.D. Ill. July 30, 2020); *see also, e.g.,* KSA 60-3306 (Kansas); Minn. Stat. § 544.41 (Minnesota); Mo. Ann. Stat. § 537.762 (Missouri); N.J. Stat. § 2A:58C-2 (New Jersey); N.D. Cent. Code § 28-01.3-04 (North Dakota). Other states provide exceptions where the manufacturer is insolvent or is not subject to the jurisdiction of the court. *See, e.g.,* Ind. Code § 34-20-2-4; Iowa Code § 613.18; KRS 411.340 (Kentucky); Md. Code Ann., Cts. & Jud. Proc. § 5-405; N.C.G.S.A. § 99B-2(a) (North Carolina); O.R.C. 2307.78(B) (Ohio); Okla. Stat. tit. 76, § 52.2.E (Oklahoma); Tenn. Code Ann. §29-28-106 (Tennessee); Texas CPRC Sec. 82.003(a)(7); Wis. Stat. § 895.047 (Wisconsin). Insolvency and the jurisdiction of the various defendants are issues that are particularly relevant here given that it does not appear that all defendants have waived personal jurisdiction across all states implicated in this MDL and the relative solvency of each defendant is the subject of discovery. Regardless, the precise application of the various innocent seller statutes requires an in-depth analysis that is not accomplished in the chart put forth by the Retail Pharmacy Defendants.

H. Wholesalers Are Not Too "Unique" To Be Liable

Wholesaler Defendants' suggestion that their role in the distribution chain is so "unique" that they cannot possibly be liable in any way (*see* Wholesaler Br. at 4-5) must be rejected for several reasons. First and foremost, there is nothing new or novel about seeking to hold liable entities at the wholesale distribution level of a supply chain. Courts throughout the country have found wholesalers operating at the distribution level – including some of these very same Defendants here – liable under a variety of state law claims. *See, e.g.*, *Ebin v. Kangadis Family Mgmt LLC*, 45 S. Supp. 3d 395, 398-401 (S.D.N.Y. 2014) (certifying nationwide class of

consumers who purchased allegedly mislabeled olive oil that had been distributed by defendant, even though defendant did not sell directly to consumers); *In re Takata Airbags Prods. Liab. Litig.*, No. 15-02599-MD, 2020 WL 2892366 (S.D. Fla. June 1, 2020) (refusing to dismiss consumer class claims against distributor of vehicles with purportedly defective airbags under fraud and other theories); *Fagan v. AmerisourceBergen Corp.*, 356 F. Supp. 2d 198 (E.D.N.Y. 2004) (consumer stated negligence claim against distributor and pharmacy for sale of counterfeit drugs); *In re Chinese Manufactured Drywall Prods. Liab. Litig.*, 680 F. Supp. 2d 780 (E.D. La. 2010) (denying motions to dismiss various state law claims against homebuilders, distributors, and manufacturers); *In re Nat'l Prescription Opiate Litig.*, 440 F. Supp. 3d 773 (N.D. Ohio 2020) (finding TPPs adequately alleged duty owed by wholesale distributors to state claim). Further, as discussed *supra* under particular counts, Wholesaler Defendants are properly liable under the state law theories alleged in the Master Complaints.

I. Defendants' Jurisdictional Arguments Are Premature and Meritless

In a footnote, Manufacturer Defendants argue the Court should grant Defendants leave to file a supplemental memorandum (on top of their existing 120 pages of briefing, and improperly appended 112 pages of legal charts) to argue personal jurisdiction challenges. *See* Mfr. Br. at 9 n.12. Defendants' belated request should be rejected for multiple reasons. First, the number of pages was negotiated at length and approved by the Court and it is procedurally improper to revisit this issue, let alone through a footnote. Second, Defendants are incorrect that the Court has barred jurisdictional challenges. To the contrary, the Court has stated multiple times that no defenses have been barred and each will be addressed in due course.

Defendants' main jurisdictional argument – that "ELMC and MMMC name several out-of-state Defendants from whom *none* of the named class representative Plaintiffs allege that they made purchases in New Jersey" (Mfr. Br. at 9 n.12) – is premature and meritless. A multi-state

class action need not have a class representative from every possible state so long as the interests of class members from each state are aligned. *See, e.g.*, *O'Neill v. Standard Homeopathic Co.*, 346 F. Supp. 3d 511 (S.D.N.Y. Sept. 28, 2018) (putative consumer class representatives had standing to assert claims related to products they themselves did not purchase). And, in any event, this determination is to be made at the class certification stage, not the pleadings stage.

Further, it is well-established that, in a multi-district litigation, the "transferee court can exercise personal jurisdiction to the same extent that the transferor court could." *In re Automotive Refinishing Paint Antitrust Litig.*, 358 F.3d 288, 297 n.11 (3d Cir. 2004).

Finally, Defendants' argument that some foreign Defendants lack "the requisite jurisdictional connection to the United States," is belied by the well-pleaded allegations, which demonstrate a sufficient nexus to the United States for each Defendant. *See generally* ELMC ¶¶ 48-145; PIMC ¶¶ 18-133; MMMC ¶¶ 20-106; *see, e.g.*, *In re Liquid Aluminum Sulfate Antitrust Litig.*, No. 16-MD-2687, 2019 WL 1125589 (D.N.J. Mar. 11, 2019) (Linares, C.J.) (denying Rule 12(b)(2) motion on basis of allegations). At worst, this would be a fact-intensive question for which jurisdictional discovery would be needed before the Court were to issue any ruling, even on a Rule 12(b)(2) motion. *See, e.g.*, *In re Diisocynates Antitrust Litig.*, MDL No. 2862, 2020 WL 1140245, at *7 (W.D. Pa. Mar. 9, 2020). Thus, no defendant is prejudiced at this point prior to jurisdictional discovery.

In sum, the Court should disregard Manufacturer Defendants' footnoted arguments concerning premature, and ultimately meritless, jurisdictional arguments.

CONCLUSION

For the foregoing reasons, Defendants' Motions to Dismiss should be denied.

Dated: September 18, 2020 Respectfully Submitted,

/s/ Ruben Honik
Ruben Honik
GOLOMB & HONIK, P.C.
1835 Market Street, Ste. 2900
Philadelphia, PA 19103
Phone (215) 985-9177
rhonik@golombhonik.com

/s/ Daniel Nigh
Daniel Nigh
LEVIN, PAPANTONIO, THOMAS, MITCHELL RAFFERTY & PROCTOR, P.A.
316 South Baylen Street
Pensacola, FL 32502
Phone: (850) 435-7013
dnigh@levinlaw.com

/s/ Adam Slater

Adam Slater
MAZIE, SLATER, KATZ & FREEMAN, LLC
103 Eisenhower Pkwy, 2nd Flr.
Roseland, NJ 07068
Phone (973) 228-9898
aslater@mazieslater.com

/s/ Conlee S. Whiteley

Conlee S. Whiteley
KANNER & WHITELEY, LLC
701 Camp Street
New Orleans, LA 70130
Phone: (504)-524-5777
c.whiteley@kanner-law.com

MDL Plaintiffs' Co-Lead Counsel, on behalf of the Plaintiffs' Executive Committee and all Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on September 18, 2020, a true and correct copy of the foregoing was filed and served upon all counsel via operation of the CM/ECF system for the United States District Court for the District of New Jersey.

/s/ David J. Stanoch
David J. Stanoch